COMPARISON OF MR PROCTOGRAPHY AND BARIUM PROCTOGRAPHY IN PATIENTS WITH PELVIC FLOOR DISORDERS

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF MD RADIODIAGNOSIS (BRANCH VIII) EXAMINATION OF THE TAMIL NADU DR M.G.R MEDICAL UNIVERSITY, CHENNAI TO BE HELD IN APRIL 2017

DECLARATION:

I declare that the dissertation entitled "Comparison of MR proctography and barium proctography in patients with pelvic floor disorders" is my original work submitted in partial fulfilment of the requirement for MD Radiodiagnosis (Branch VIII) Degree Examination of the Tamil Nadu Dr M.G.R Medical University, Chennai to be held in April 2017.

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CERTIFICATE:

This is to certify that the dissertation entitled "Comparison of MR proctography and barium proctography in patients with pelvic floor disorders" is the bonafide original work of Dr. Deepa Rebecca Korula submitted in partial fulfilment of the requirement for MD Radiodiagnosis (Branch VIII) Degree Examination of the Tamil Nadu Dr M.G.R Medical University, Chennai to be held in April 2017.

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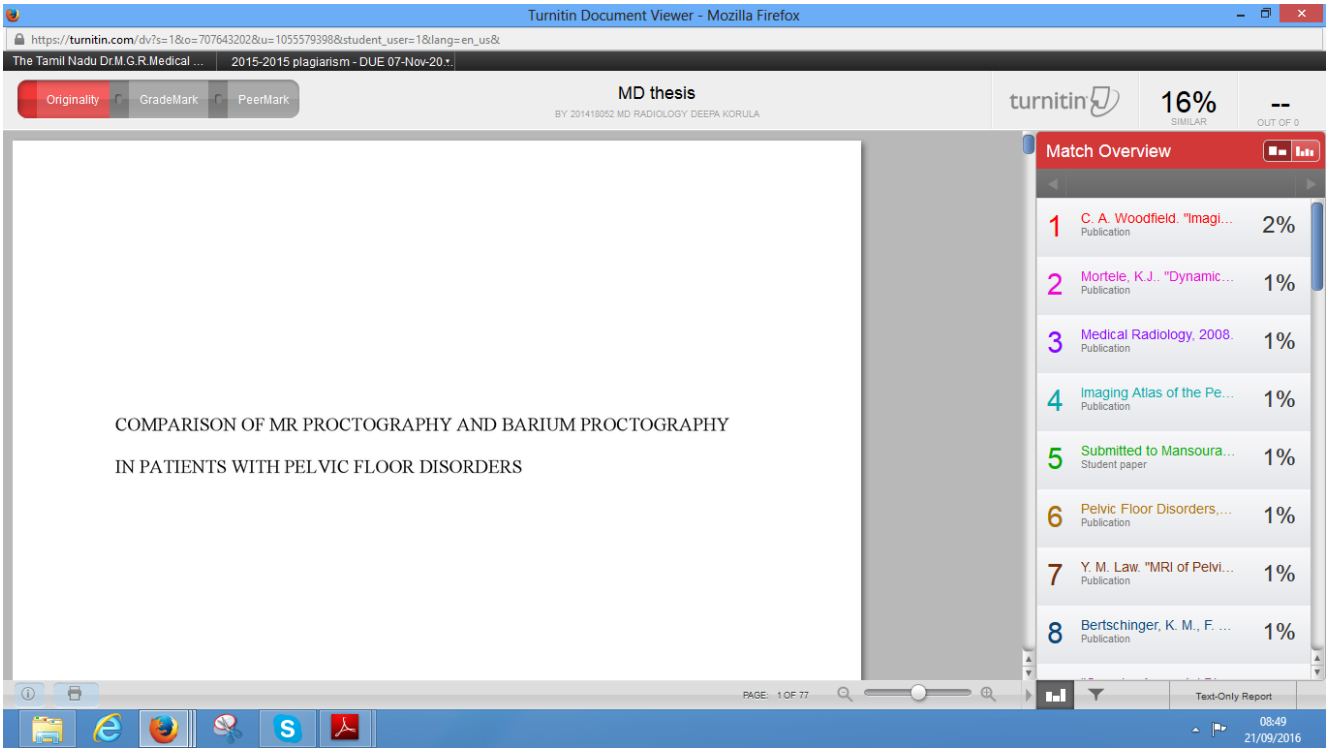
ORIGINALITY CERTIFICATE:



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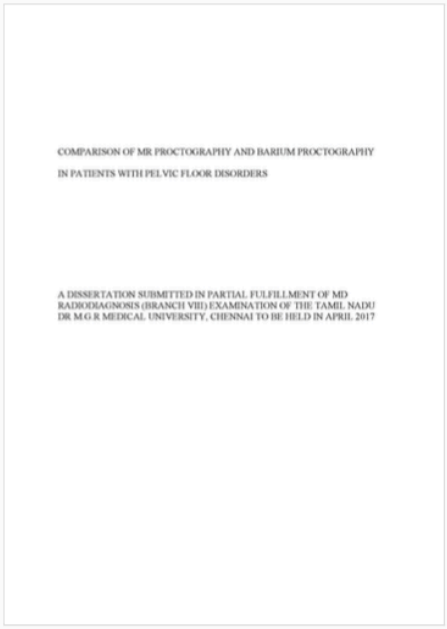

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Contents

Introduction:

Pelvic floor disorders are a common health problem especially among women with the current prevalence worldwide of ~ 9%-50% (1) The pelvic floor is made up of various muscles, ligaments and connective tissues that support the pelvic organs. Damage to any of these structures may lead to pelvic floor dysfunction. In simple terms, it refers to a subset of disorders that affect the pelvic floor that may lead to abnormalities of bowel and bladder emptying and storage with or without associated pelvic pain.

The common symptoms include constipation, straining, lower back pain, urinary urgency, frequency and hesitancy, pain during intercourse, pelvic floor spasm etc. They may occur as a side effect to many drugs as well such as tricylcic antidepressants.

Pelvic floor disorders increases with age and is predicted to increase subsequently in the Western world due to the changing demographics. It is estimated that more than 15 % of multiparous women are affected and around 10-20% seek medical care in gastroenterology clinics.(2)

AIMS AND OBJECTIVES:

1) To compare the imaging features of pelvic floor disorders seen in MR defecogram and barium defecogram.

2) To assess patient perception of these procedures.

JUSTIFICATON FOR THE STUDY:

When the patient's symptoms are mild, both physical examination as well as conventional imaging may be sufficient for the diagnosis. However when the patient's symptoms are moderate or severe, routine examination may underestimate the compartments involved and lead to inaccurate diagnosis. The recurrence rate post surgery is said to be ~10-30% and this may be attributed to multi-compartment involvement which may have been missed at the time of diagnosis. Conventional barium proctography can assess only the posterior compartment. MRI is a very usefully technique for assessment of all the compartments in patients with multi-compartment involvement.

The concordance between clinical assessment and findings at dynamic MRI for disease staging has been found to be good with a slightly weaker correlation for findings in the posterior compartment (20) (21). MR defecography has been found to show more extensive abnormalities than physical examination alone (22) (23) .

Dynamic MRI has been said to change the surgical management is around 67 % of cases compared to 40 % with conventional fluoroscopic studies. (24). For example, the treatment for an uncomplicated cystocele is retropubic colposuspension, however when the paravaginal fascia is detached, fascial repair is required. Anterior rectocele repair by surgery may be performed either by transanal or transvaginal approach. If there is a rectal intussusception, posterior fixation of the rectum may be included as well.

Various other incidental pathologies may also be detected on MRI, which gives it superiority over other conventional imaging modalities. These may include urethral diverticula,

malignant lesions, fibroids, etc just to name a few. This knowledge will additionally help in treatment and planning further management.

MR imaging does not involve any radiation while barium proctography does, typically ~ 2-3 mSv. Thus the patient is safe from radiation hazard, though it may be a small dose. MRI can thus be used in pregnant patients and in follow up imaging as well.

Review of literature:

PRESENT KNOWLEDGE:

MR proctography is said to overcome certain limitations of barium proctograghy. However there are varying opinions on this and literature gives us mixed reviews as stated below:

1. Rectoceles:

M Kelvin et al(21) showed that both tests were in complete agreement on the presence of rectoceles and the mean difference in the extent of the rectocele (R = 0.40, p value 0.02, mean size of the rectocele was 2.85 for MR, 2.45 for barium).

Pilkington et al(24)showed that rectoceles were extremely common and the measure of agreement on the presence of rectoceles was substantial(k= 0.690) . The mean difference measured on both the tests was found to be 0.20 cm. A Bland Altman plot constructed to show the mean difference in rectocele size against their mean, showed that 95% of the differences in size measured on barium and MR proctography lie between 2.8 and -2.4 cm

which may be clinically significant. They found that rectocele emptying was more frequent on barium proctography and there was poor agreement between barium and MR proctography is this aspect(k=0.12).

In another study done in Germany by Lienemann et al(22), it was found that the sensitivity and specificity of detecting rectoceles on barium defecography was 50% and 93% respectively as compared to MR colplocystorectography which was 69% and 96 % respectively

2. Enterocele,Sigmoidocele:

Pilkington et al(24) found enteroceles to occur relatively rarely and there was substantial agreement between the both the tests. However the number of cases was small and barium proctography identified three cases (43%) that were missed on MR proctography.

Cappabianca et al(27) published that inspite of a 100% specificity of MR defecography in the detection of eneteroceles and sigmoidoceles, the sensitivity was found to be 65% and 82% respectively, showing an inferior diagnostic capacity as compared to entero-colpo-cysto-defecography.

M Kelvin et al(21) mentioned that dynamic MR imaging underestimated the extent of the prolapse by 10-15% as compared to barium imaging. The mean difference in the extent of enteroceles and sigmoidoceles was 0.75(p=0.45).

3. Cystocele:

M Kelvin et al(21) showed MR proctography underestimated the extent of the prolapse by 10-15% as compared to dynamic fluoroscopic cystocolpoproctography imaging with a difference in mean extent of 0.50(p-0.03)This study also found that without sufficient emptying, a cystocele may prevent the recognition of an enterocele, peritoneocele or a rectocele.

Leinemann et al (22)showed the sensitivity and specificity of diagnosing a cystocele on barium proctography was 91% and 90% respectively as compared to 94% and 100% on MR proctography. Out of 33 cystoceles diagnosed on clinical examination, 31 were detected on both dynamic fluoroscopy and MR colpocystorectography.

A comparative study of colpocystodefecography and dynamic fast MR imaging done on 35 women by Vanbeckevoort et al(37), showed an agreement of 100 % in the diagnosis of cystocele.

On conventional barium defecography, a cystocele cannot be diagnosed as the bladder is not opacified, hence MR defecography is superior is this aspect.

4. Rectal prolapse and intusucception:

Pilkington et al(24) showed the measurement of agreement between barium proctogaphy and MR proctography for rectal intussusception was fair(k=0.209). However MR proctography missed 31% (11/35) of cases detected on barium proctography. In 10 of these cases there was failure of rectal evacuation on MR proctography.

A study done on nineteen patients by P.V Fotiet al(38)showed there was significant difference in rectal prolapse between conventional defecography and MR defecography.

5. Uterine and vaginal vault prolapse:

Lienemann et al(22) concluded that a vaginal vault prolapse was more accurately seen on MR than with dynamic fluoroscopy with a sensitivity and specificity of 94% and 100% with the former and 94% and 90% with the latter.

A comparative study of colpocystodefecography and dynamic fast MR imaging done on 35 women by Vanbeckevoort et al(37), showed an agreement of 91% and disagreement of 9% in vaginal vault prolapse. This study also found the sensitivity of MR imaging to be higher during maximal pelvic strain(60%) as compared to imaging during voiding and defecating(13%) with the specificity being 100% in both situations. Their results also supported the fact that topographical changes involving the levator ani muscles and vagina occur with a uterine prolapse and hence MR imaging may be a superior test and used for assessing the efficacy of surgical prolapse repair.

6. Pelvic floor dyssynergia/ Anismus:

MRI is a reliable test for pelvic floor dyssynergia and recommended when there is a discrepancy betwen clinical impression and other anorectal physiological tests.

Pilkington et al(24) showed anismus (spastic pelvic floor) was reported in 43% cases on MR proctography and 29% cases on barium proctography, the measure of agreement being moderate(k=0.493).

Dynamic MR images reveal a smaller change in the anorectal angle because the puborectalis muscle fails to relax during evacuation and thus more sequences are required to eliminate a small volume of contrast.(2)

A similar study to the one conducted by us, comparing barium proctography and MRI proctography has been done in the UK by Pilkington et al(24) however there have been no such studies described in the Indian population. In this study 71 consecutive patients referred for barium proctography were recruited for MR proctography. 42 patients had both the studies. They found that 29% of patients had complete rectal emptying on barium and 2 % had complete emptying on MR proctography. MRI missed ~ 31% of rectal intussusceptions that were detected on the barium proctography. However there was a limitation as ten of these cases could not achieve rectal evacuation. The level of agreement between MR and barium for rectal intussuception was found to be fair, however MR was found to underestimate the grade. Rectoceles were detected in both however there were differences in the size on both the studies. They also found that anismus was seen in 29% of patients on barium and 43 % of patients on MR. A feedback form from the patients showed that the patients found the study done in MR less embarrassing than barium, however rectal evacuation was tougher, likely due to the supine position.

There is no such study published comparing both the tests in the India till date, hence our study would be the first in the Indian population. Currently in our institution we have not

started MRI defecography as a routine investigation and barium defecography is currently the investigation ordered for pelvic floor disorders. If the results of MRI were found comparable to the barium defecography in this study, the feasibility of starting MRI defecography as a routine test for pelvic floor disorders in our institution would be considered.

Prevalence in India:

A study done by Krishna Rao et al on over 1000 married women in Karnataka showed that ~ 21 % of women had symptoms of either pelvic organ prolapse or urinary incontinence. The prevalence of urinary incontinence in India has been reported to be between 10-68% (3),(4) uterine prolapse 7.6 % and incontinence 1.3%. (5). Another study done in Pondicherry showed a genital prolapse prevalence of 18.8%. (6). They also found that 26.7% of patients had cystoceles, 15.6 % had rectoceles, 6.7 % had cystorectocele and 4.4 % had enterocele and rectocele.

Risk factors:

There a number of factors which contribute to pelvic floor failure which may be congenital or acquired. Patients may have a genetic predisposition to alteration in the collagen and elastin metabolism leading to abnormal extracellular matrix, which commonly results in urinary incontinence and pelvic organ prolapse. The main risk factors include female sex, increasing age, menopause, obesity, pregnancy and parity which reduce the muscle tone as a result of

increased intra-abdominal pressure. Vaginal delivery can cause neuromuscular damage to the pelvic floor, though not all women who undergo vaginal delivery develop pelvic floor dysfunction.

Chronic obstructive pulmonary disease and constipation may lead to chronic straining, which may in turn lead to pudendal neuropathy. A history of previous pelvic surgery, predominantly hysterectomy is a major risk factor leading to weakening of the pubovesical and rectovaginal fasciae.

The various types of pelvic floor disorders commonly include rectocele, cystocele, enterocele intusucception, prolapse, descending pelvic floor syndrome and spastic pelvic floor syndrome.

These disorders may manifest with urinary tract symptoms such as straining, urge and stress incontinence, post void maneuvers, bowel symptoms such as fecal incontinence, difficulty in defecating, rectal prolapse or sexual symptoms such as dyspareunia and difficult intercourse. Almost 10 % of patients undergo surgery for these disorders and ~ 30% will have at least two surgeries in their lifetime.(2)

ANATOMY:

The pelvic floor is broadly divided into three compartments. The bladder and urethra form the anterior compartment. The uterus, cervix and vagina form the middle compartment and the posterior compartment comprises of the rectum and anal canal. The attachment of the fascia, muscles and the ligaments to the bony pelvis form the support for these structures.

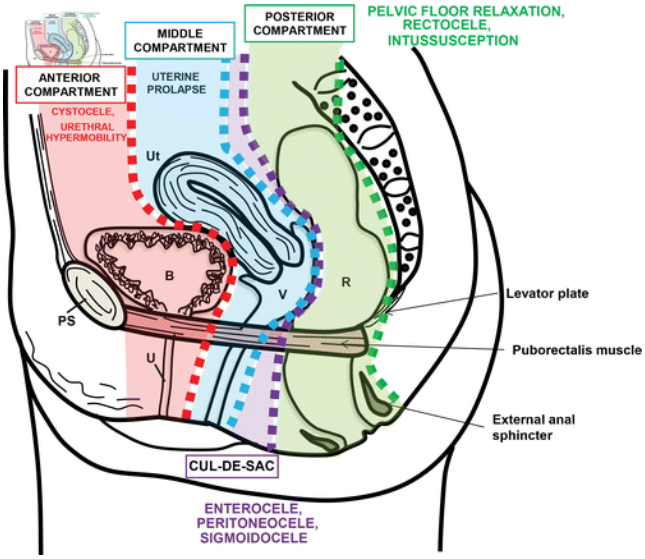


Figure 1 – Compartments (*MR Imaging–based Assessment of the Female Pelvic Floor – Garcia et all Radiographics, Sept-Oct 2014)*

Pelvic floor:

The pelvic floor is a multilayer system that provides support both actively and passively.

This includes:

1. Pelvic diaphragm
2. Pelvic fascia
3. Urogenital diaphragm

Active support is provided by the muscles of the pelvic floor, predominantly the levator ani. The passive support is provided by the ligaments and the fasciae.

The pelvic fascia, pelvic diaphragm and the urogenital diaphragm from the three layers of the pelvic floor from top to bottom.

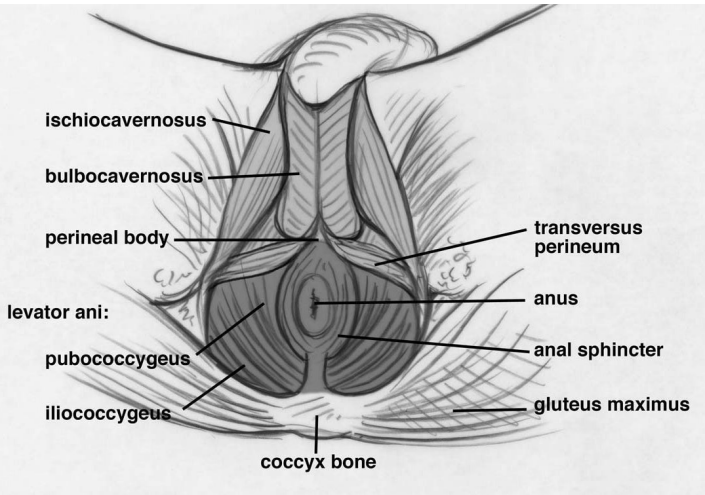


Figure 2 - MALE PELVIC FLOOR

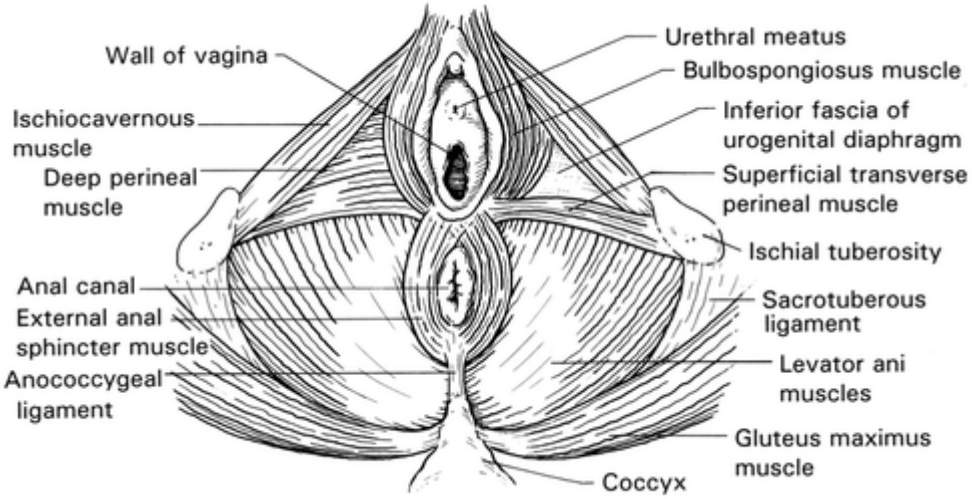


Figure 3 - FEMALE PELVIC FLOOR

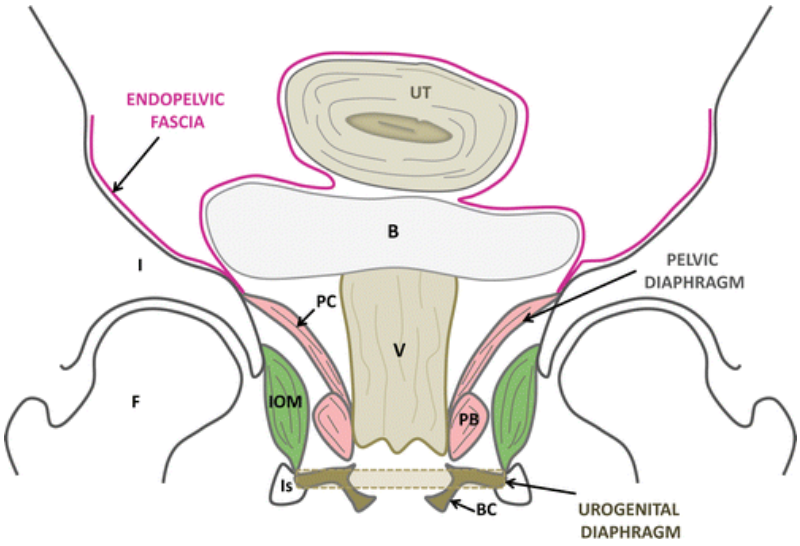
(Courtesy - anatomy of the pelvic floor – beyond basics physical therapy)

Pelvic fascia:

The components of the pelvic fascia include the pubocervical fascia, the rectovaginal fascia, parametrium, paracolpium and the tendineus arcus fascia.

Overall, it is a fine structure which encases the pelvic viscera and provides support to the pelvic organs and maintains their anatomic relationship.

However, this is ideally not a true fascia and has been described as endopelvic connective tissue on histology.



(Figure 4 – Anatomy, Schematic diagram in the coronal plane, PC – puborectalis muscle, PC – pubococcygeus muscle, Is- ischial ramus, IOM – internal obturator muscle, I- iliacus muscle, BC – bulbocavernosus muscle, F – femur, UT – uterus, B – bladder)

(MR Imaging–based Assessment of the Female Pelvic Floor Laura García et al Radiographics Sept 2014)

The cardinal and the uterosacral ligaments together form an important supporting system to the upper one third of the vagina and the uterus. The pericervical ring is formed by the

uterosacral ligament with fibres involving the cervix and the upper vagina. The uterosacral ligaments merge with the presacral fascia and the cardinal ligaments on both sides merge with the parietal fascia.

Uterine and vaginal prolapse may occur as a result of lesions in the pubocervical ring.

Pelvic Diaphragm:

The levator ani and the coccygeus muscles make up the pelvic diaphragm.

The levator ani is the primary muscle of the pelvic diaphragm and is attached to the pubis and on both sides laterally to the arcus tendineus levator ani. This muscle helps to maintain the tone and helps close the urogenital hiatus.

Various parts of the levator ani muscle have been described.

The pubococcygeus muscle forms the anteromedial part and is a thick bundle of fibres arising from the pubis and attaching to the anorectum and vagina. It has a sling like configuration and this makes it an important structure contributory to prolapsed and urinary incontinence. The anorectal and urogenital hiatus are closed by the contraction of the pubococcygeus muscle. This enables support during rest and in situations where the intra-abdominal pressure is increased.

This muscle is made up of the pubovaginal, puborectalis and pubococcygeal muscles.

Pubovaginal muscle – helps support the vagina and inserts onto the posterior and lateral vaginal wall. It has a horse-shoe shape.

Puborectalis muscle- this muscle is considered a part of the external anal sphincter and controls fecal descent.

Pubococcygeal part – this muscle also facilitates the passage of stool and inserts on the coccyx.

This muscle is Y shaped. The levator hiatus is the space between the lateral components and contains the urethra, vagina and the rectum.

The less dynamic levator ani muscle is the iliococcygeus muscle which is located above the pubococcygeus muscle. Its origin is from the arcus tendineus levator ani extending posterior to the rectum.

Posterior to the levator ani is the coccygeus muscle which is less dynamic . This originated from the ischial spines and extends to the lateral margins of the coccyx.

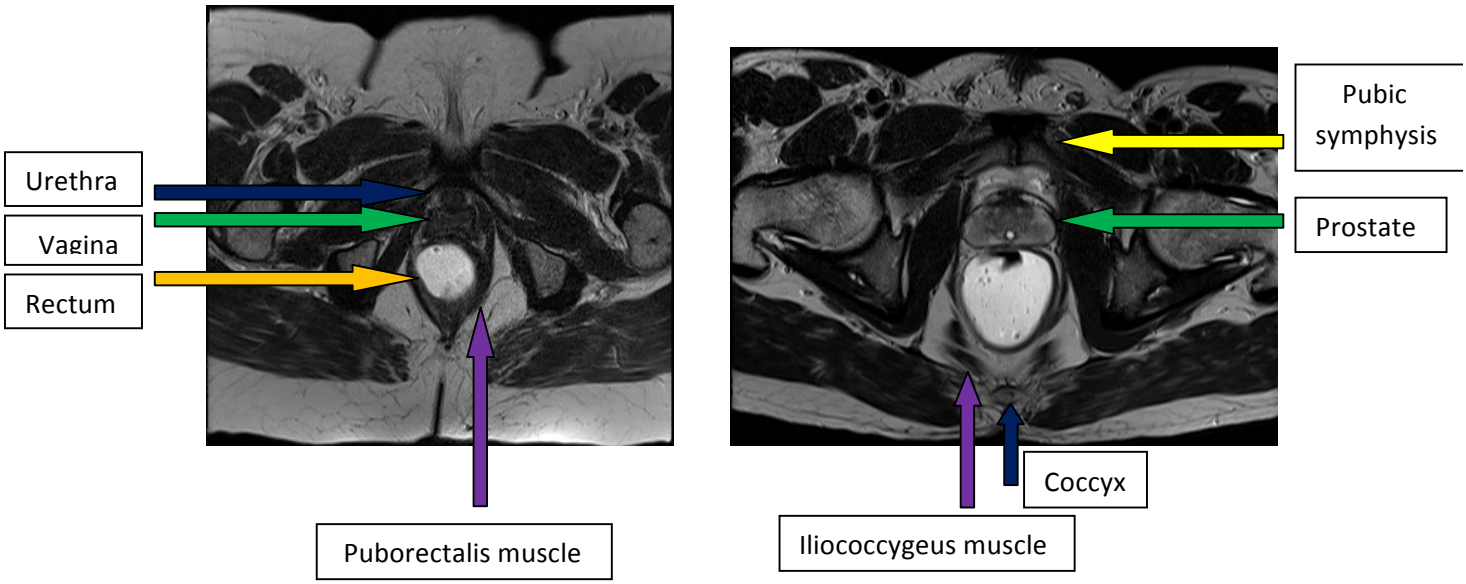


Figure 5

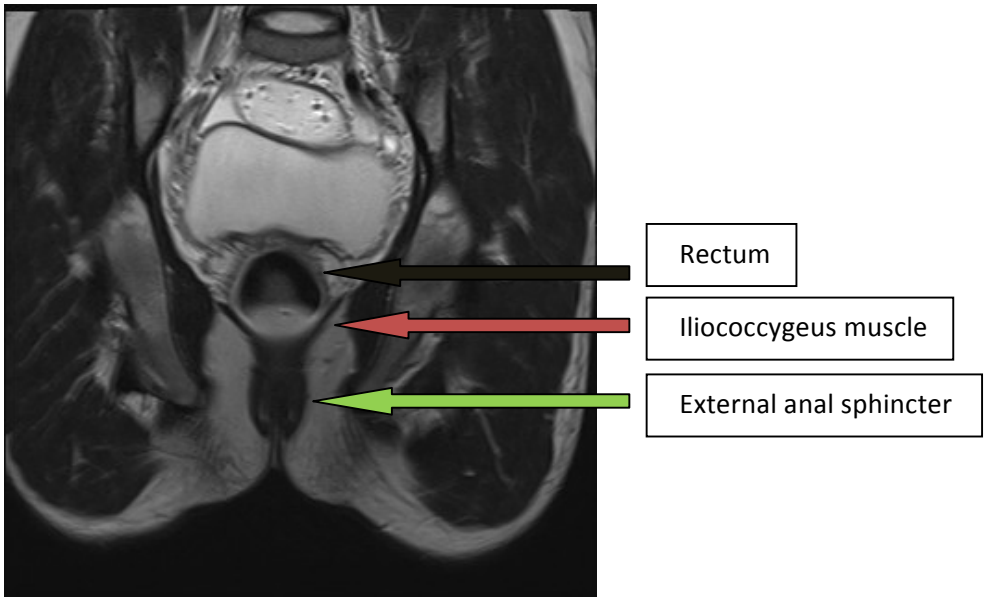


Figure 6

The nerve supply to the levator ani comes from the sacral nerve roots S2-S4 through the pudendal nerve which cross the pelvic floor. As a result they may be compressed during labour leading to injury.

Urogenital diaphragm:

The urogenital diaphragm is made up of several muscles. The deep transverse muscle of the perineum is the principle muscle and originates from the inner surface of the ischial ramus and extends along the perineal membrane. The rest of the muscles make up the urethral and the urethrovaginal sphincter.

The urogenital diaphragm is also known as the perineal membrane and has a triangular appearance from the pubic symphysis and the ischiopubic ramus to the posterior perineal body. It is situated caudal to the pelvic diaphragm and ventral to the external anal sphincter

and perineal body. It is attached to the surrounding structures such as the perineal body,external anal sphincter, vagina and the bulbocavernous muscle.

The urethral sphincter:

The urethral sphincter is important for the maintanence of urinary continence. The internal urethral sphincter is made up of smooth muscle and is under involuntary control. It is continuous with the detrusor muscle. The external urethral sphincter consists of striated muscle and is under voluntary control. This sphincter is more intricate in women than men.(7) Urinary incontinence may be a result of improper functioning of the urethral sphincter.

Anal canal and sphincters:

The anal canal consists of the internal and external sphincters which are two partially overlapping tubes. The anal canal follows the shape of a flattened cylinder and the overall length is ~ 3-5 cm, extending from the upper border of the puborectalis to the anal verge. The rectum lies in the midline almost perpendicular to the anal canal at the anorectal junction. The anal canal is angled posteriorly ~ 30 degrees in the sagittal plane.(8)

The internal anal sphincter measures ~ 3 cm in length and is shorter than the external anal sphincter. The puborectalis muscle wraps around the upper portion which extends above the external sphincter. This sphincter is made up of circular muscle which is continuous with the circular muscle of the rectum and contributes ~ 85 % to the resting anal tone (5). Acting

alone is relatively weak and hence requires the contribution of the voluntary external sphincter.

On MR imaging, the internal anal sphincter has intermediate signal on T2 weighted images, high signal on T2-fat suppressed images and shows intense enhancement on post contrast imaging.

The external anal sphincter extends from the lower border of the puborectalis to the anal verge and is comprised of circular muscle fibres which are striated. This contributes to only ~ 15 % of the resting anal tone. The true external sphincter lies inferior to the puborectalis and is differentiated from the puborectalis on coronal sections by a notch of fat.

The external anal sphincter is said to have three parts, the deep portion, superficial portion and the subcutaneous portion. The deep part is essential for continence while the middle portion anchors the anal canal in an anteroposterior direction. This is possible due to it's extensions anteriorly to the perineal body and posteriorly to the anococcygeal body.

The subcutaneous portion encircles the anal verge on parasaggital sections while on axial sections it is incomplete posteriorly. In men it has fibres extending to the coccyx posteriorly and hooks under the bulbospongiosis.

On MR imaging, the external anal sphincter is hypointense on T2-weighted imaging and shows less enhancement on post contrast imaging as compared to the internal anal sphincter.

The intersphincteric space is a fat layer between both the sphincters. The superifical fascia of the levator ani gives off fibres which fuse with the outer coat of the longitudinal muscle of the rectum. This then continues below as the conjoint longitudinal coat and divides the inter-

sphincteric space into the inner and outer potential spaces. The lower portion then inserts onto the subcutaneous portion of the external sphincter and functions to retract the anal canal during defecation.

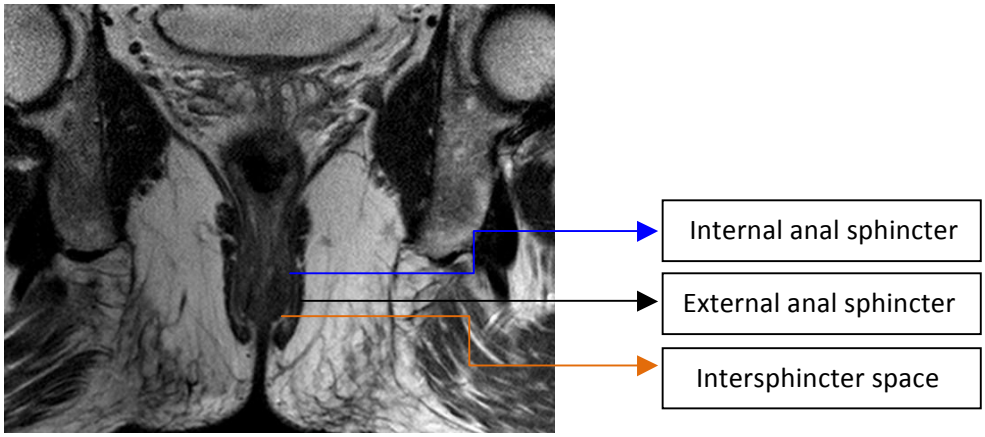


Figure 7

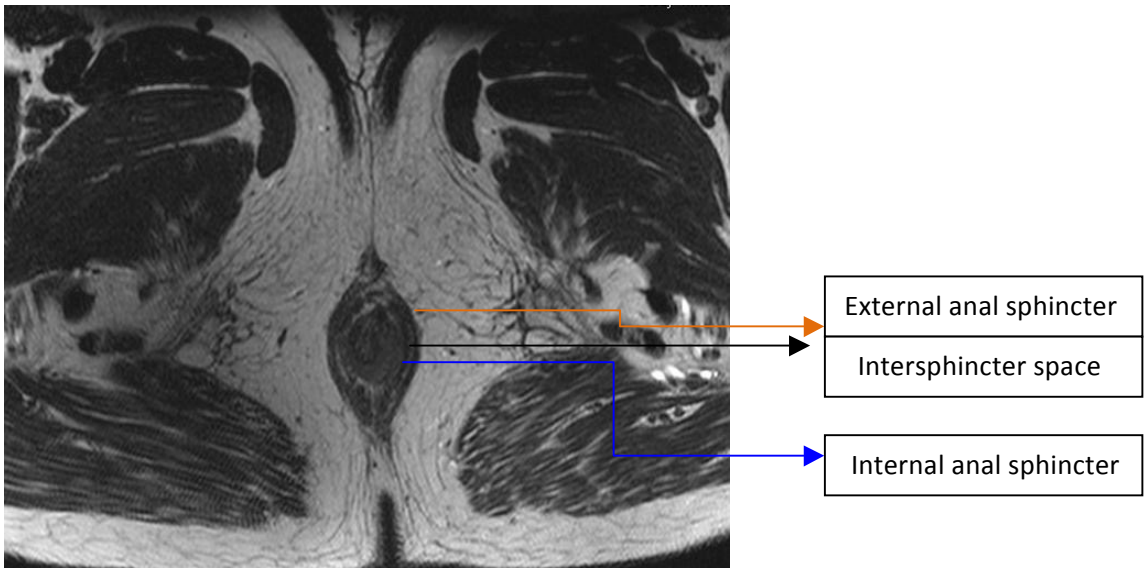


Figure 8

Vagina:

The walls of the vagina are made up of smooth muscle, collagen and elastin. The pelvic fascia, pericervical ring, urogential diaphragm and arcus tendineus levator ani contribute to supporting the vagina.

According to DeLacey, there are three levels of vaginal support: (21)

a) The ureterosacral cardinal complex – level I
b) The arcus tendineus fascia pelvis – level II
c) The perineal membrane and the arcua tendineus levator ani – level III

On MR imaging, the intact vagina has a H – shape on axial images. If there is a tear in the rectovaginal fascia or the pubococcygeal muscle, the vagina will lose its shape and configuration and retract towards the lesion.

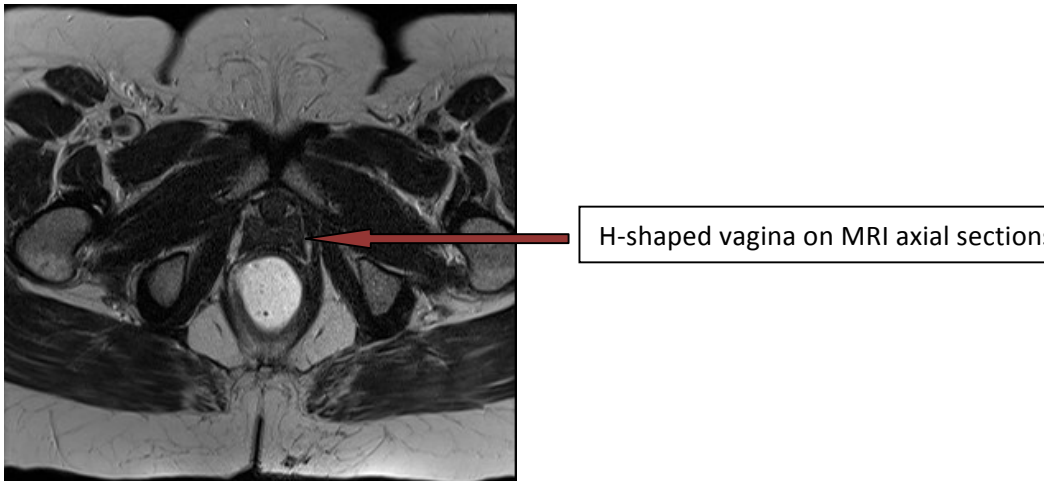


Figure 9 - Vagina

MRI PROCTOGRAPHY TECHNIQUES:

There are varying opinions regarding the method of performing MR proctography. Most studies use the closed configuration magnets. In this method, the patient lies down in the magnet in supine position. The vertically open-configuration magnets have an advantage as they allow imaging in the truly physiological position which is the erect position, however this technique is less available.

There are various other technical factors, the choice of which are still under debate. There include the type and use of the contrast material used, the imaging plane and the various maneuvers performed, the use of markers, catheters or tampons to identify the pelvic structures, etc.

1. Open – configuration magnet:

- Usually performed with a 0.5T superconducting, open configuration unit. Between the two magnet rings , an MR compatible adjustable wooden seat is set up and on the chair a single loop transmit-receive coil is placed such that the patient is sitting over the opening of the coil.
- Usually using a fast T1-weighted spoiled gradient, a sagittal sequence is acquired . The mid-sagittal slice is chosen and one slice is repeated 15 times as the patient is instructed through the manoeuvres of squeeze, strain and defecation. The

resulting images are displayed in a cine loop mode to observe relationship of anatomy during manoeuvres. After the examination, a set of axial T2-weighted fast spin-echo

sequences may be acquired to evaluate anatomical relationships of pelvic floor organs and the pelvic floor muscles.

2. Closed – configuration magnet:
    - This is done with the patient in supine position and is generally obtained on a 1.5 T system using a phased array surface receiver coil. No opacification of the bladder, vagina, small bowel or rectum is typically needed however some investigators prefer to fill the rectum with ultrasound gel or barium sulphate paste in order to facilitate rectal distention.
    - Half- fourier single- shot turbo spin- echo or fast spin-echo images (e.g HASTE, SSFSE) are taken in the sagittal plane during pelvic floor relaxation and pelvic strain, after an initial localizer.

Supine Vs Sitting MRI proctography:

Varying opinions have been voiced regarding the better position for imaging and few studies have also been conducted in order to demonstrate the superior position. One study conducted (10) showed that supine MRI resulted in an underestimation of disease severity. However they found that relevant findings seen in the sitting position were not missed on supine MR imaging. They found that although most abnormalities could be seen in both positions, they were best seen in the sitting position. Overall, sitting MR was not found superior to the supine position for demonstrating clinically relevant findings but it did show a larger degree of pelvic laxity.

Another study done on 200 patients (10) comparing both the positions (largest study published so far) showed that MR in supine position may underestimate the fixed descent and a statistically significant difference does exist when the pelvic floor descent is evaluated in sitting versus supine position. This study found there was no significant difference in the percentage of cystoceles detected, though the position of the bladder was significantly different in both positions.

There was also no significant difference found in the measurement of the anorectal junction in both positions which suggests that the maximum level of the pelvic floor descent was more influenced by the muscle elasticity and pelvic floor voluntary contractions than by gravity.

They found that there was a significant difference in the comparison of the grades of dynamic descent between the supine and sitting position and that MR in supine position may overestimate the grade of dynamic descent of the pelvic floor.

They thus concluded that MR defecography in the sitting position may represent a useful tool to accurately diagnose and grade pelvic organ descent.

A study on 38 patients (11)described that in both the supine and sitting position, evaluation of all three compartments of the pelvic floor was possible. They found that all intussusceptions were depicted only on sitting position and the sensitivity of supine MR imaging for the depiction of disorders was poor to moderate but when small anterior rectoceles, small bladder descents, small vaginal vault and rectal descents which may have no clinical relevance were excluded from the analysis, the sensitivity of supine MR imaging increased to 100 % for demonstrating bladder descents and anterior rectoceles and to 96% for the depiction of rectal descents.

Patient position :

In the supine technique, a pillow is placed under the gluteus which elevates it, simulating a sanitary toilet. The pubic symphysis must be in the middle of the phase array coil.

Patient preparation:

There are varying opinions on this aspect as well. Some investigators recommend a four hour fasting and bowel preparation with glycerin suppository 2- 8 hours prior to the study. Some investigators are of the opinion that fasting or bowel preparation is not required.

Prior to the study, patients are asked to empty their bladder as a full bladder may block the descent of a rectocele or uterine prolapse and this may be missed.

Some propose the use of 10 mg of intravenous butylescopolamine to prevent intestinal peristalsis and uterine contractions, however this is again subjective.

The preparation includes injecting around 10 ml of intravaginal ultrasound gel to distend the vaginal fornix and 4 syringes of 60 ml of contrast gel into the rectum. The rectal contrast in injected until the patient feels fullness and the urge to defecate.

Instructions to the patient:

It is important to use easy instructions in their own language in order for the patients to understand and follow accurately, for example for valsalva, squeeze and defecation, words such as bear down as hard as you can, squeeze your anal muscle, relax etc may be used.

Patient's must be instructed to initiate the dynamic movement when they hear the technologist's command and the instructions must be well audible in order to ensure the right maneuver at the right time of the study.

Position and technique :

In the supine technique, a pillow is placed under the gluteus which elevates it, simulating a sanitary toilet. The pubic symphysis must be in the middle of the phase array coil.

Analysis and imaging of the pelvic floor is done both at rest and with dynamic imaging.

An example of a recommended protocols include:

At rest:

- Sagittal T2-weighted fast spin echo (FOV 26; thickness 4.0 _ 0.2; matrix 384 _ 224; NEX 4; repetition time [TR] 4400 and echo time [TE]102; 24 slices)
- Axial T2-weighted fast spin echo (FOV 26:thickness 4.0 _ 0.5; matrix 256 _ 192; NEX 3; TR 4400 and TE 90; 30 slices)
-Coronal T2-weighted fast spin echo (FOV 24;thickness 4.0 _ 0.2; matrix 384 _ 224; NEX 4;TR 4200 and TE 101; 20 slices)

Dynamic protocol:

- Sagittal FIESTA sequence at rest (FOV 30;thickness 10.0 _ 5.0; matrix 320 _ 320; NEX 1; TE minimum; 1 slices) (to make sure the image includes the anorectal angle, bladder, urethra, and vagina)

- Sagittal Valsalva (same protocol as earlier with 20 repeats)

- Sagittal squeeze (same protocol as earlier with 50 repeats)

- Sagittal defecation (same protocol as earlier with 170 repeats)

(2)

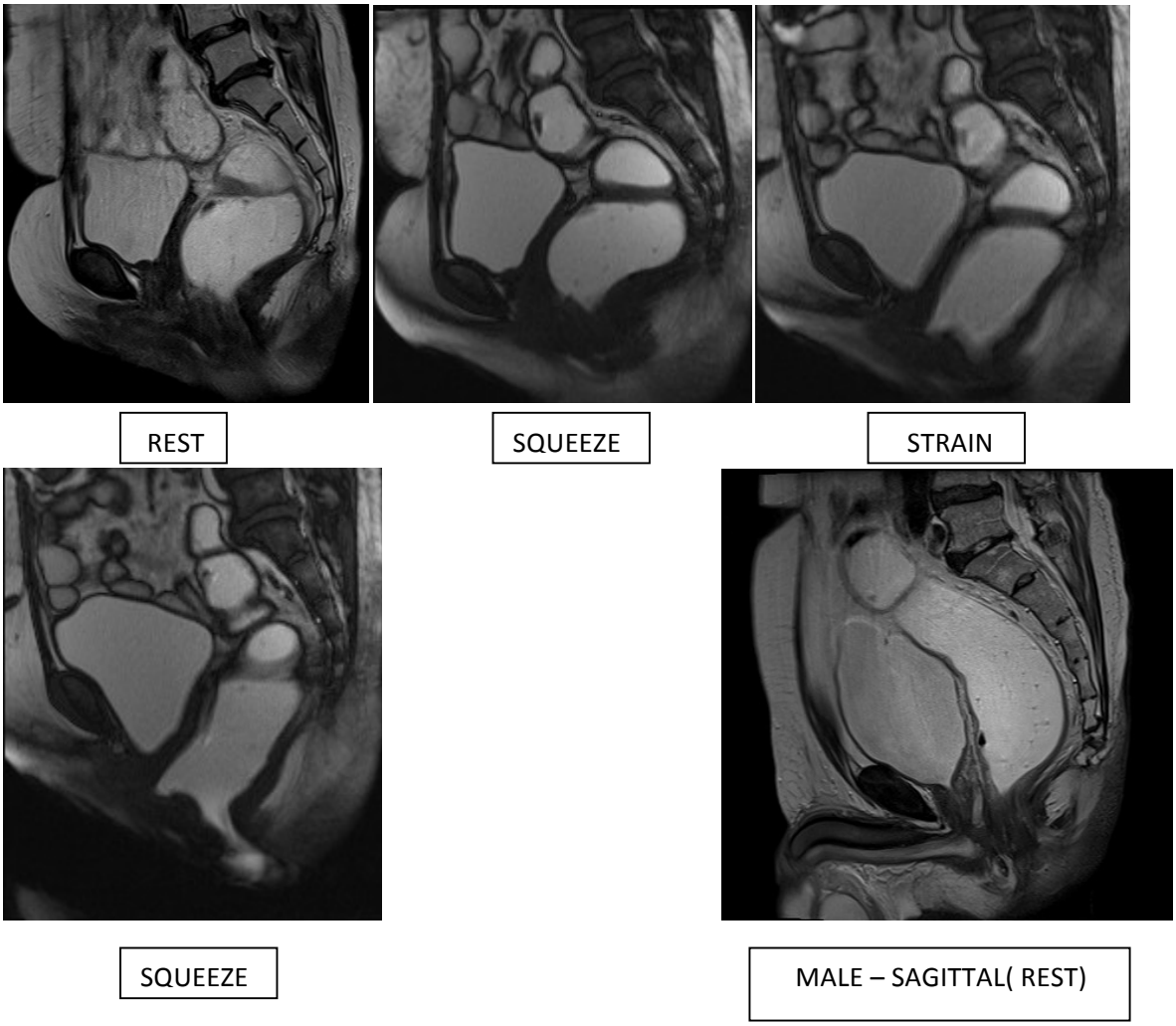


Figure 10 - Dynamic phases on MRI

BARIUM PROCTOGRAPHY TECHNIQUE:

This is also known as “defecography” and refers to the fluoroscopic assessment of rectal evacuation. The population that undergo this test include patients with a history of constipation or defecatory dysfunction. This imaging technique involves radiation(~ 2-3 mSv)

Barium contrast is used to opacify the rectum and the test is conducted with the patient seated on a commode. Images are obtained during the phases of rest, squeezing, straining, defecation and post defecation.

In our institution, this test is done on a routine basis. The patient is asked to take a liquid diet the day prior to the study. On the day of the study, initially a rectal water enema is given to the patient to ensure that the bowels are empty. The patient is then made to lie in the left lateral position and ~ 300 ml of thick barium paste is injected into the rectum using a Foley’s catheter. The paste may also be inserted using plastic syringe connected to the catheter (13). In our institution 95 % w/v barium paste is used, which is similar to the consistency of normal stool. When the stimulus to evacuate is achieved, the injection of barium may be stopped and the study may commence.

The fluoroscopy table is made vertical and a special commode is attached to the footboard. The patient is then made to sit on the commode in the right lateral position. When the radiogenic tube is centred on the pelvis in correct position, the first image at neutral position is obtained. The patient is then instructed to squeeze, strain and defecate step by step and

respective dynamic images are obtained till the rectum is empty. Without interruption, this process usually takes approximately one minute. The patient is then asked to go and evacuate the rectum completely in the bathroom and a post evacuation image is taken to assess contrast trapping.

Frontal views have been described to be useful in certain situations such as for depiction of lateral prolapsed or enteroceles.

Figure 11 - Barium defecography set up in our institution

Evaluation of the pelvic floor by this study involves the identification of certain bony landmarks such as the pubic symphysis, the ischial tuberosity, the coccyx, etc.

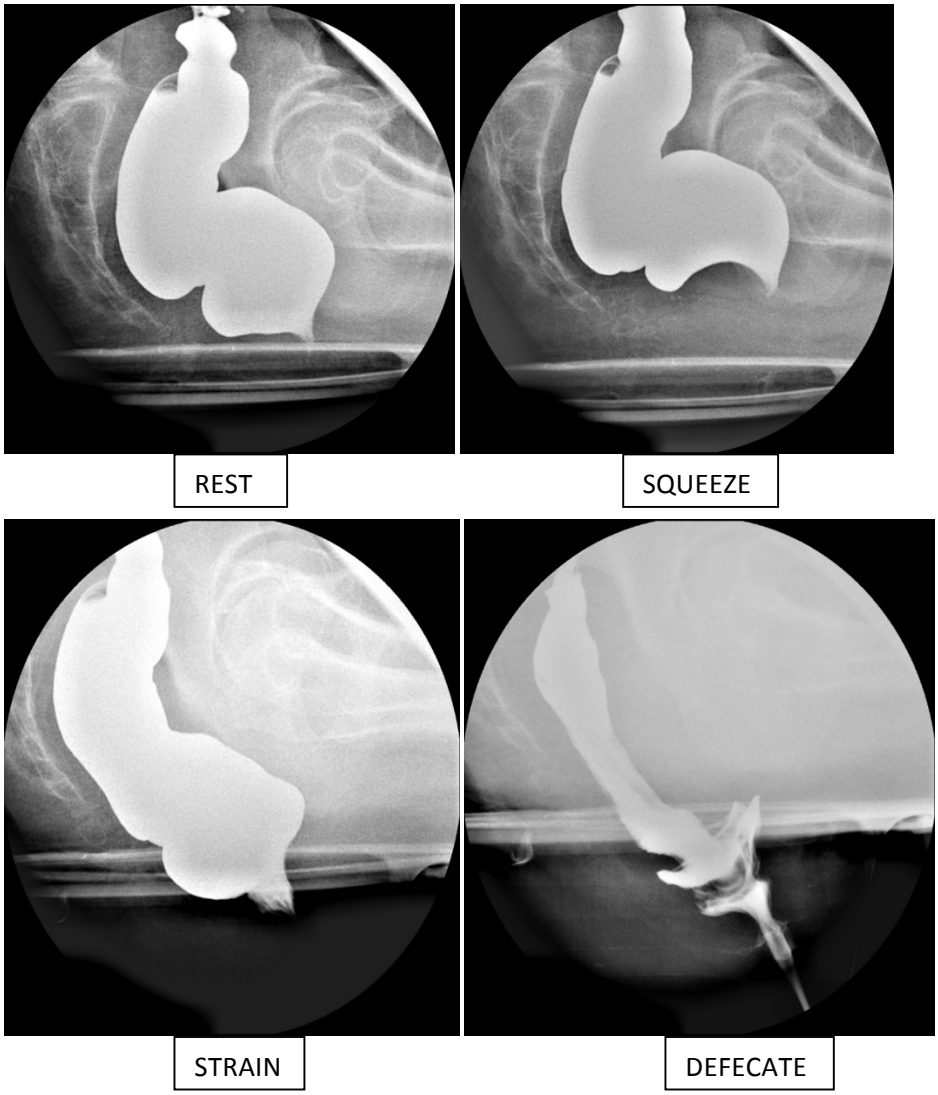


Figure 12 - Conventional barium proctography study

Similar to MRI assessment as will be described below, parameters such as the anorectal junction, degree of pelvic floor descent, the pubococcygeal line, the midpubic line, etc may be assessed. Rectoceles, rectal intussusceptions and rectal prolapse may be easily identified in this study.

For the assessment of coexisting anterior and middle compartment pathology, contrast opacification of additional pelvic organs may be required such as the vagina and the urinary bladder. Evaluation of the opacified bladder and rectum under fluoroscopy is referred to as

cystoproctography and evaluation of the opacified rectum, vagina and bladder is known as cystocolpoproctography. However these techniques are not practiced in our institution.

Flouroscopic studies have been widely used and are more or less considered the gold standard for the diagnosis of pelvic floor disorders.

They have been found to reveal more extensive pelvic floor abnormalities that physical examination alone with high observer accuracy and said to alter the management in upto 40 % of patients (1)

Accurate preoperative diagnosis of pelvic floor abnormalities is important for the accurate surgical intervention to be carried out. Limitations of physical examination and failure to identify defects in all three compartments of the pelvic floor are the main factors contributory to surgical failure.

Barium studies are relatively operator dependent and one of the more difficult investigations for radiologists to master(31). In our country economic factors play a significant role in continued use of barium defecography.(31)

OTHER IMAGING MODALITIES:

A complete history and physical examination is required for the evaluation of pelvic floor disorders. However the degree of pelvic organ prolapse may not always be apparent. Since the treatment is usually surgical correction, pre-operative assessment of the entire pelvis is required to guide surgical repair. There are various imaging techniques to image the pelvic floor, which have been evolving over time.

These include barium proctography, ultrasound, video-urodynamic studies, computed tomography and the MRI.

1. Ultrasound: Ultrasound has the advantage of no radiation, being easily available and relatively easy to perform. Various techniques may be used such as transabdominal, transvaginal, transperineal and endoanal with or without 3D techniques.

Advantages:

- Using transabdominal ultrasound, the pre and post void bladder volumes can be assessed in patients with urinary incontinence or retention. The morphology of the bladder and urethrovesical junction mobility can also be assessed with ultrasound.

- Transvaginal ultrasound can calculate the urethral volume, which correlates well with the urethral pressure measurements on urodynamic testing.

- Synthetic implants such slings and meshes can be visualized on ultrasound, so it is a good modality in assessing patients post surgical treatment.

- The integrity of the internal and external anal sphincter can be assessed well on endoanal ultrasound, especially in patients with fecal incontinence. Anal sphincter defects are seen as muscular interruptions and ultrasound is reported to have sensitivities and specificities upto 90 % for the same(14)(15).

- The 3D and 4D ultrasound have improved the sonographic evaluation of pelvic floor disorders. The pubic symphysis is used as the landmark and at the level of the vaginal

introitus, the transducer is positioned in a mid sagittal orientation. Real time images of 3D cine loops are obtained during rest, squeeze and strain.

Disadvantages:

-the transducer may compress the pelvic structures, for example the bladder, urethra and vaginal canal which may results in wrong assessment of the organ position and morphology.

-the limited field of view with ultrasound also limits the overall assessment.

-in pelvic organ prolapse, the role of ultrasound is still under question. A study on 145 women with pelvic organ prolapsed by Dietz et all found that translabial ultrasound had a good correlation with the clinical staging of prolapse in all the compartments. (16). However a more recent study of 31women with obstructed defecation found that translabial ultrasound had a poor correlation with evacuation proctography in the assessment and detection of rectoceles, true rectal prolapse and rectal intussuception. (17)

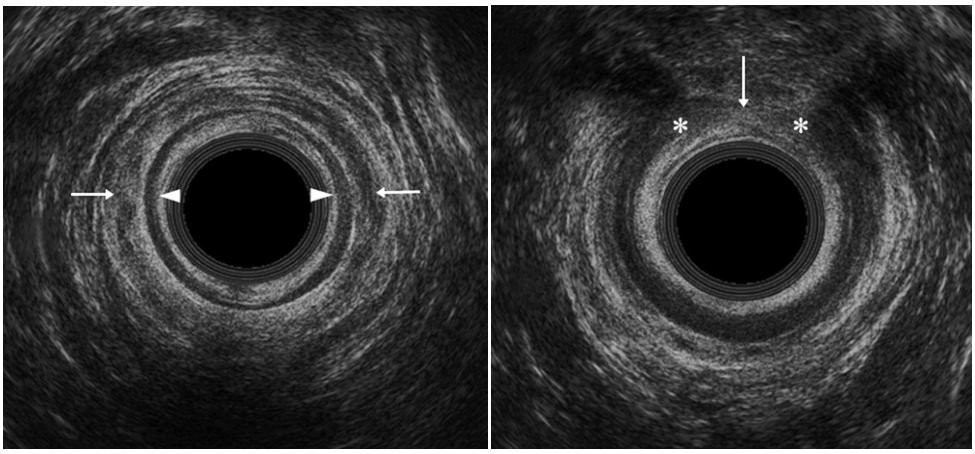


Figure 13 - ***Transverse endo-anal ultrasound image at level of mid anal canal shows anterior defect of internal anal sphincter muscle (arrow). Astericks shows the edges of internal sphincter muscle (AJR June 2010)***

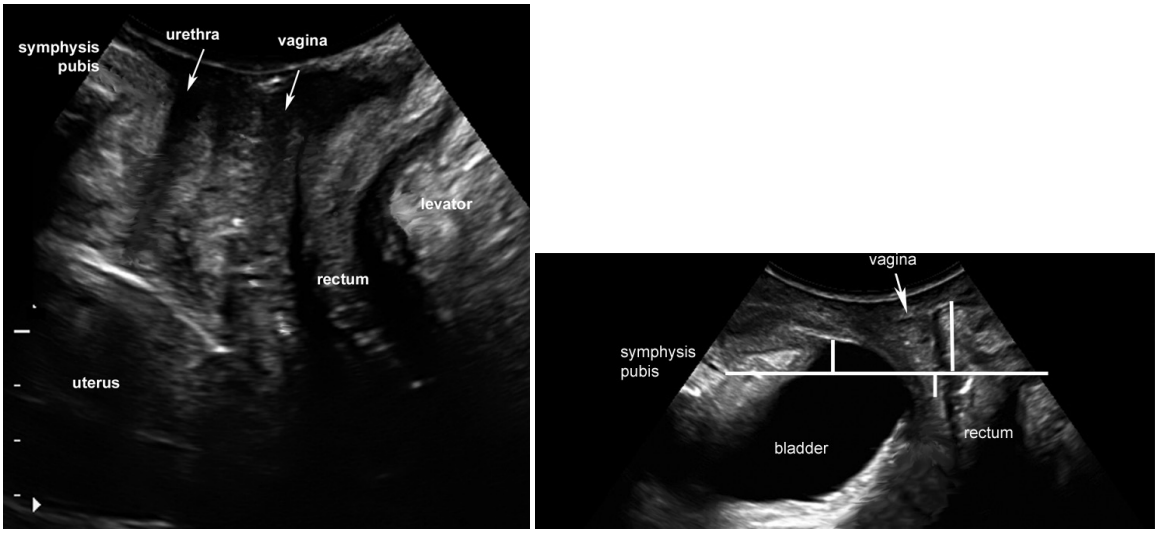


Figure 14 - ***third degree cystocele, grade two uterine descent and a third degree rectocele***

(courtesy – Ultrasound imaging of the pelvic floor – Anneke Steensma)

2.Voiding cystourethrography (VCUG): Several fluoroscopy techniques may be used to assess pelvic floor disorders which include voiding cystourethrography, evacuation proctography, cystocolpoproctography, cystoproctography, etc. The advantages of flouroscopy are the ability to assess patients in the standing or sitting positions , the easy availability and the fact that it is relatively easy to perform. However there are certain disadvantages which include the invasive nature of the study, the use of ionizing radiation and the inability to evaluate all three pelvic compartments at the same time.

In patients with urinary incontinence, VCUG may be used to detect cystoceles. The bladder is filled with iodinated contrast and images are taken with the patient in the lateral standing position during rest, stress and voiding. The urethrovesical junction mobility, the maximal bladder descent, vesicoureteric reflux and urethral diverticula may be assessed. VCUG has a reported accuracy of 65 % for detecting urethral diverticula and 58 % compared with the clinical Q-tip test for diagnosing urethral hypermobility.(19)

3. Video-urodynamic – this technique combines urodynamics and fluoroscopy and may provide additional information with regard to the relationship between the pelvic anatomy and function of the bladder and urethra.

Urodynamic tests assess the bladder, sphincters and the urethra and looks at the ability to store and release urine. Most tests focus on the ability of the bladder to hold and empty urine steadily and completely . Involuntary contractions of the bladder and the detrusor instability in patients with urge urinary incontinence are assessed. The cystometric summaries of the bladder, intra-abdominal and urethral pressures can be evaluated.

Video-urodynamic tests take videos and images of the bladder during filling and emptying. This may be assessed either by X-ray or by ultrasound.

4. CT - Computed tomography may be used to assess the anatomy of the pelvic floor and particularly to rule out bony abnormalities. However, it is inferior to MRI in soft tissue resolution and dynamic sequences involve considerable amount of radiation, hence it is not a preferred modality in the assessment of pelvic floor disorders.

MRI INTERPRETATION:

The MR images are reviewed in both the static and dynamic sequences. The initial T2 weighted images are used to identify lesions in the fasciae, ligaments and the supporting muscles.

a) **Pubococcygeal line (PCL):** defined as the line that connects the inferior portion of the pubic symphysis to the last horizontal coccygeal joint. The PCL is the most commonly used reference line for the assessment of pelvic floor disorders.

Normally, in a continent woman, the uterus, bladder and the vaginal vault remain above the PCL. The descent of pelvic organs is conventionally measured along a perpendicular line from the organ to the PCL and this should be measured both at rest and during maximal strain.

For the anterior compartment, the reference point is the posterior and most inferior part o the bladder base.

In the middle compartment, the reference point is the most anterior and inferior aspect of the cervix or postero-superior vaginal apex in patients who have undergone hysterectomy.

For the posterior compartment, the reference point is the anterior aspect of the anorectal junction.

Slight descent during valsalva maneuver is normal but if there is more than 1-2 cm descent below the PCL, the pelvic floor is likely to be weakened. If the descent is more than 2 cms, surgery may be required.

H line: defined as the distance between the inferior border of the pubic symphysis and the posterior wall of the rectum at the level of the anorectal junction. It represents the most

caudal part of the levator ani group (puborectalis muscle) and allows the assessment of the widening of the pelvic sling in AP diameter during straining. A diameter greater than 6 cm is taken as abnormal.

M line: defined as the vertical line drawn perpendicularly from the PCL to the posterior end of the H line. It represents the measure of the muscular pelvic floor descent and when the length exceeds 2 cm, it is abnormal.

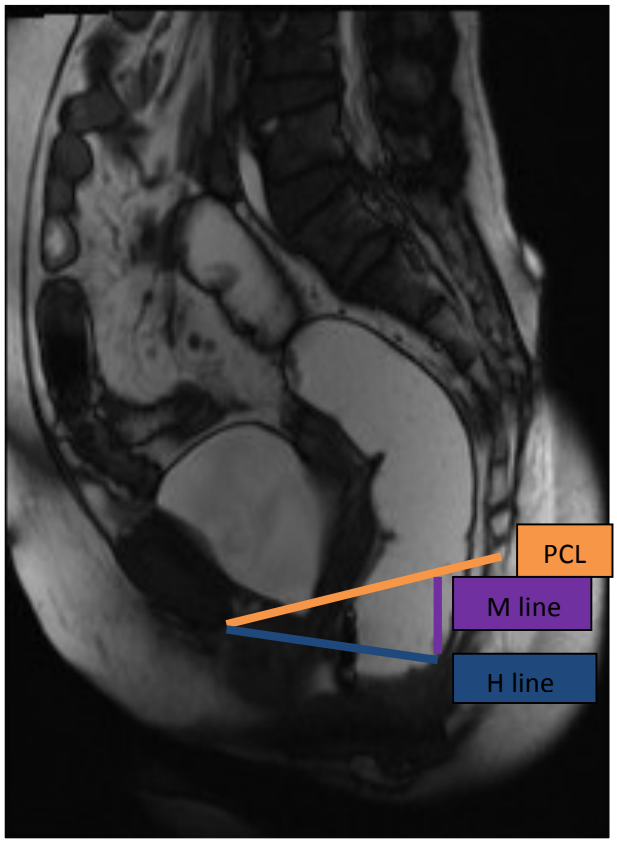


Figure 15 - Reference lines

Assessment of the anterior compartment:

Cystocele – is referred to the abnormal descent of the urinary bladder at rest or during straining. It can result from tearing of the pubocervical fascia or the levator ani muscle.

Grading of cystoceles is done by assessing the distance of the bladder base from the PCL and may be graded as mild, moderate or severe.

Grade	Distance from the PCL
Mild	1-3 cm below
Moderate	3-6 cm below
Severe	>6 cm below

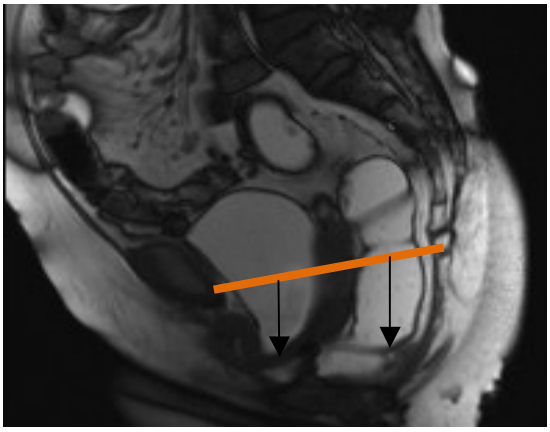


Figure 16 - *MRI Saggital T2 sections showing cystocele and pelvic floor descent*

Along with prolapse, patients may have incontinence as well so study on urinary incontinence must be included. During pelvic floor contraction, on sagittal imaging, the normal urethra is slightly vertical and anterior to the bladder base.

Urethral hypermobility results from a loss of urethral integrity related to the sphincter and the anterior fascia of the bladder and is best visualized during dynamic imaging with the valsalva maneuver. It is diagnosed when the urethra rotates more than 30 degrees from rest, from the vertical to horizontal axis. Accurate diagnosis is essential as repair requires a pubocervical sling procedure.

The rest MR images are ideal for visualization of the urethra and the supporting ligaments.

The urethra in a normal patient is above or at the inferior pubic level. There is inferior descent of the urethra when there is a defect of the urethral support ligaments of the paravaginal fascia.

Beaking of the bladder neck of saggital views at rest or straining may be normal and is not indicative of incontinence. Widening and filling of the proximal urethra may be seen in funneling or opening of the urethrovesical junction. This may be seen at rest or during valsalva and may be seen in patients with urinary incontinence.

Assessment of the middle compartment:

Uterine and vaginal vault prolapse may result from weakness of the pubocervical fascia, rectovaginal fascia, paracolpium and the parametrium.

The H and M lines are elongated and the vagina may be horizontal in patients with middle compartment weakness.

Prolapse is measured on the sagittal plane, perpendicularly from the PCL to the anteroinferior aspect of the cervix or the posterosuperior vaginal apex in a patient who has undergone hysterectomy. The vaginal apex should ideally be 1 cm above the PCL post hysterectomy.

The vaginal walls are everted and uterus may be seen as a bulging mass in cases of procidentia or complete uterine prolapse.

Grade	Distance from the PCL
Mild	1-3 cm below
Moderate	3-6 cm below
Severe	>6 cm below

Peritoneocele is defined as the protrusion of the peritoneal fat between the rectum and the vagina with descent of the pouch of douglas into the rectovaginal space.

The pouch of douglas is said to be the most inferior aspect of the peritoneal cavity and is located at the level of the posterior vaginal fornix. If there is inferior herniation of the peritoneal pouch along the anterior rectal wall with an increased distance between the vagina and rectum and wide rectovaginal fossa, a peritoneocele may be diagnosed.

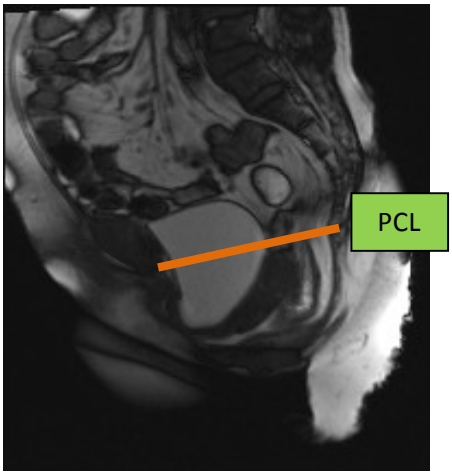


Figure 17- PCL

GRADING	
Till lower third of vagina	Mild
Till the perineum	Moderate
Beyond the anal canal	Severe

Along with peritoneal fat, there may be descent of small bowel loops (enteroceles) or large bowel loops(eg. sigmoidocele, cecocele).

Enteroceles may be classified as follow:

Grade I – herniation upto the distal third of the vagina.

Grade 2 – herniation upto the perineum.

Grade 3 – herniation beyond the anal canal.

Assessment of the posterior compartment:

The posterior compartment may be assessed at rest or doing evacuation.

Assessment during rest:

1. The outline of the anterior rectal wall.
2. The anorectal junction.
3. Evaluation of the levator plate.

Assessment during evacuation:

1. The anorectal angle.
2. The length of the anal canal opening.
3. The anorectal junction in relation to the PCL.
4. Degree of rectal evacuation

Inability to retain endorectal contrast during the various stages of rest, valsalva and defecation should also be documented.

Anal canal :

-the normal length of the anal canal at rest measures ~ 16 and 22 mm in women and men respectively. The length of the canal reduces during contraction to ~ 14 mm in women and 17 mm in men.

Anorectal angle:

- defined as the angle between the midline of the anal canal and a line tangent to the posterior rectal wall.

At rest the normal angle measures ~ 70-134 degrees. On squeezing, there is a normal reduction in the angle which is representative of the normal puborectalis contraction. During defecation, the puborectalis muscle relaxes with a normal increase in the anorectal angle.

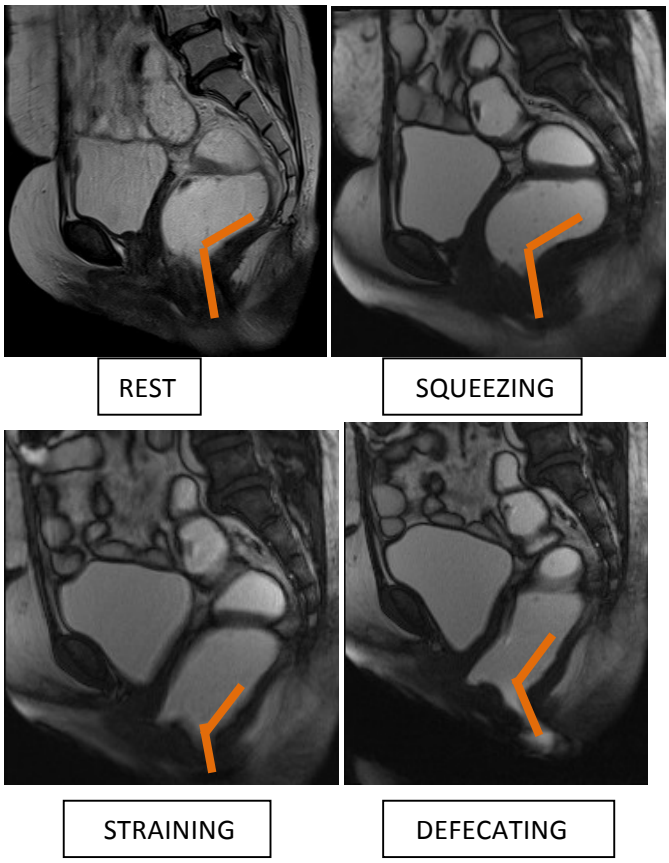


Figure 18 – Anorectal angle in different phases

OTHER COMMON PATHOLOGIES:

Rectocele:

Damage to the rectovaginal fascia may cause an abnormal bulge of the anterior rectal wall into the posterior vaginal wall. It is measured as the protrusion from the line drawn upward from the anterior wall on sagittal images.Rectoceles are an important cause of obstructed defecation , however rectoceles less than 2 cm may be clinically insignificant and asymptomatic . Posterior rectoceles are relatively uncommon.

The size of the rectocele, degree of rectal emptying and retention of contrast are important factors in the planning for treatment and can be evaluated well on MR imaging.

Grade	Depth of wall protrusion
Small	<2 cm
Medium	2-4 cm
Large	>4 cm

Rectal intussusception:

This may also cause mechanical stool obstruction leading to difficulty in defecation. It can occur with infolding of the full thickness of the rectal wall into the rectum (intrarectal) or into the anal canal (intra-anal). If it occurs beyond the anus it is referred to as complete rectal prolapse.

It is important to differentiate between mucosal intussusceptions and full thickness rectal intussusception for planning for surgical treatment as mucosal prolapse requires a transanal excision on the mucosa while a full thickness rectal infolding may require rectopexy.

Pelvic floor relaxation:

Relaxation of the pelvic floor, also known as descending perineal syndrome, is a condition in which there is excessive descent of the pelvic floor at rest or during defecation. This occurs due to loss of the pelvic muscular tone and the anorectal junction is the reference point used for assessment.

Muscle weakness results in descent of the anorectal junction from the normal level and commonly does not rise above the PCL level on squeezing. On MR imaging, this is measured by the M line and a value of more than 2.5 cm is significant.

An increase in the pelvic hiatus area may be caused by bulging of the levator ani muscles. On MR imaging, this may be assessed by an increase in the value of the H line.

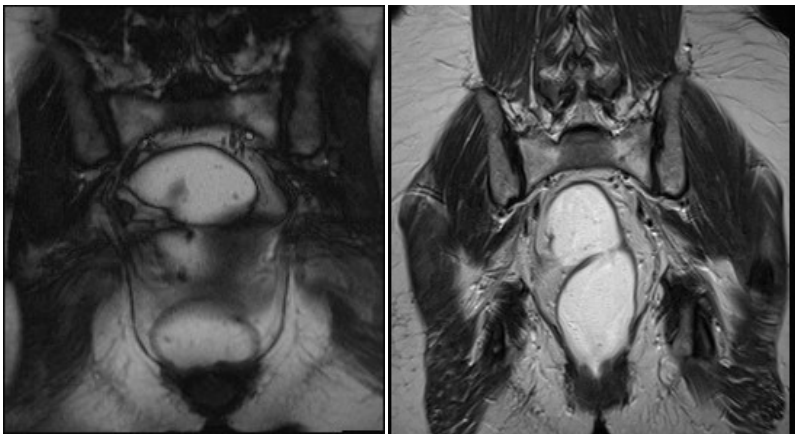


Figure 19 - Coronal section of the pelvic floor showing laxity of the pelvic floor muscles during straining

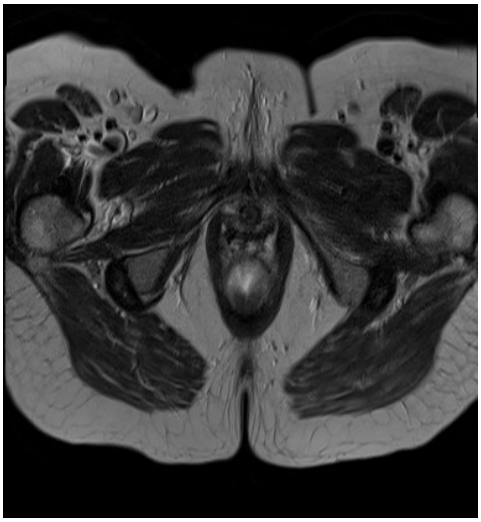


Figure 20- Axial section - Enlarged hiatus – widening of the pelvic floor

Grade	Hiatal enlargement(H line)	Pelvic floor descent(M line)
Normal	<6 cm	<2 cm
Mild	6-8 cm	2-4 cm
Moderate	8-10 cm	4-6 cm
Severe	>10 cm	>6 cm

Anismus:

Involuntary contraction of the striated pelvic floor musculature leads to this condition, which prevent normal defecation. It is also known as paradoxical puborectalis syndrome.

Prolonged and incomplete evacuation are characteristic with prolonged time between the opening of the anal canal and initiation of defecation. On MR imaging this is diagnosed by the lack of pelvic floor descent, prominent puborectalis impression and failure of opening of the anorectal angle.

Various other pathologies such a uterine, ovarian and bowel may be identified incidentally on MRI during the evaluation of pelvic floor disorders, which is an added advantage.

METHODOLOGY:

40 consecutive patients with pelvic floor disorders who underwent barium defecography were eligible for the study on consultation with the referring clinician. The barium study was done on the same day as scheduled as per routine protocol. These patients were then explained about MR defecography and written consent was obtained. If the patient was willing for the study, MR defecography was done after the barium defecography, before the next OPD visit. Detailed instructions were provided to the patient in his/her own language regarding what was to be followed during the test.

For the barium defecogram, the patient was made to lie down on the fluoroscopy machine and via a Foley's catheter, barium was instilled into the rectum till the patient felt full (as described on page) The patient was then instructed to sit on the commode and in the physiological sitting position images were acquired. The initial image was at rest position. The patient was then asked to squeeze, strain and then defecate and the respective images were taken. If satisfactory images were obtained, the patient was then asked to empty their bowel fully in the bathroom and return for a post defecation image to assess if there was contrast trapping.

For the MR study, patients were first placed in left lateral position and ultrasound gel was instilled into the rectum through a rectal catheter until the patient felt full(approximately 200-250 ml of contrast). On completion, the patient was instructed to wear an adult diaper. The patient was then taken into the MRI room and made to lie supine on the MRI gantry. The examination was done in three phases : 1)squeeze 2) strains 3)defecate. The principle investigator was present for all of the MRI studies.

The following MR sequences were taken:

T2W/HR/Sagittal - T2FSE

Trufisp cine images – Squeeze, sagittal, strain (sagittal), defecating (sagittal)

Number of repeats – 20,40,70

PROTOCOL:

i) Localiser scan (Sagittal, coronal and axial planes)

ii) MRI sequences:

1. T2 HR Sagittal

(TR – 6110 ms; TE – 81 ms; Flip angle – 1500; matrix 250 x 384, FOV – 250)

2. T2 HR Coronal:

(TR –3030 ms; TE – 94 ms; Flip angle – 1500; matrix 208 x 320, FOV - 250)

3. T2 HR Transverse:

(TR – 6110 ms; TE – 81 ms; Flip angle – 1500; matrix 250 x 384, FOV - 250)

4. T2W Sagittal- Squeeze

(TR – 47.1 ms; TE – 1.33 ms; Flip angle – 660; matrix 216 x 240, FOV - 250)

5. T2W Sagittal – Strain:

(TR – 47.1 ms; TE – 1.33 ms; Flip angle – 660; matrix 216 x 240, FOV - 250))

6. T2W Coronal – Strain:

(TR – 48.45 ms; TE –1.37 ms; Flip angle – 660; matrix 198 x 240, FOV - 230)

7. T2W Sagittal – Defecation

(TR – 47.1 ms; TE – 1.33 ms; Flip angle – [1]660; matrix 216 x 240, FOV - 250))

MRI COIL:

Anteriorly – 8 channel Body coil

Posteriorly – spine coil

Figure 21 - MRI coil used for the study

Following both barium and MR defecography the patients were provided with a questionnaire as to which test they found more comfortable and which one of the two they tests preferred.

Both the studies were the reported by two experienced gastrointestinal radiologists. The principal investigator was in charge of assigning the proformas to both the doctors to ensure there was no bias. Inter-observer variation was also assessed.

Setting:

All the barium studies were carried out in the fluoroscopy room of the radiology department of Christian Medical College, Vellore and all the MRI studies were done using a 1.5 T Siemens machine.

Study period– November 2014 to November 2016

Figure 22 - MRI 3T Siemens machine

Participants:

Study population included all consecutive patients with pelvic floor disorders who were referred for a barium defecogram to our department

Inclusion criteria:

- Patients with pelvic floor disorders who give consent to undergo both the tests.

Exclusion criteria:

- Patients in whom both tests could not be carried out
- Contraindication to MRI

Sample size:

Sample size was calculated after discussion with a statistician

Formula for test of agreement between two groups with continuous outcome and equal allocation:

$$n = \frac{2\left(z_{\alpha/2} + z_{1-\beta}\right)^2}{\left(z_{\rho_1} - z_{\rho_2}\right)^2} + \frac{3}{2}$$

Where,

$$z_{\rho_1} = \frac{1}{2}\log_e\left(\frac{1+\rho_1}{1-\rho_1}\right) \quad z_{\rho_2} = \frac{1}{2}\log_e\left(\frac{1+\rho_2}{1-\rho_2}\right)$$

ρ_1 : Inter observer agreement in group 1

ρ_2 : Inter observer agreement in group 2

α : Significance level

1- β : Power

Agreement – single group – dichotomous outcome – Kappa (testing against population value) was used

Assumption being the variables must be continuous or discrete (quantitative).

Values used:

- Population agreement – 0.4
- Sample agreement – 0.8
- Prevalence – 0.5
- Power – 80%
- Alpha error – 5 %
- 2 sided

Sample size was calculated as 39. On rounding to the nearest whole number 40 was the final value and allowing ~ a 10% difference, 35- 45 subjects was the decided range.

INSTITUTIONAL BOARD APPROVAL:

The approval of the institutional review board was obtained before starting the study (IRB Min no: 9135 dated 12.11.2014)

STATISTICAL ANALYSIS:

Statistical analysis was performed using SPSS software, version 18.

The patient questionnaire was analysed using Pearson's Chi square test.

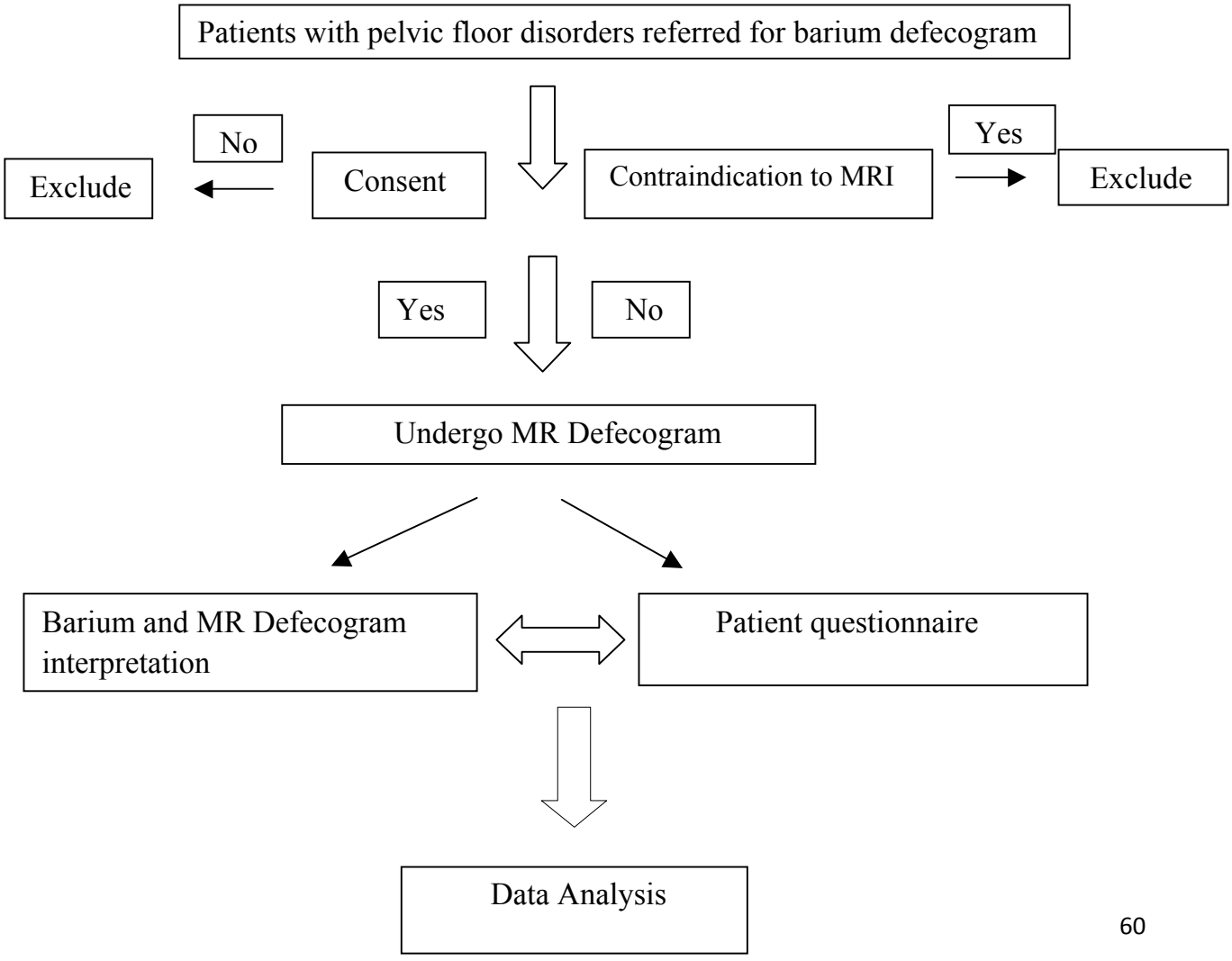
The inter-observer variability was assessed using the Kappa test.

P value of <0.05 was considered as statistically significant.

RESULTS AND CONCLUSION EXPECTED:

MR defecogram will have a superior role in the evaluation of the entire pelvic anatomy and would be a good single, non invasive, non radiation associated test that assesses all three pelvic compartments in total. It was also expected that patients would prefer MR defecogram over barium defecogram. However the expected limitation of MR defecogram would be the incomplete evacuation of rectal contrast due to lack of the physiological sitting position for defecating and small rectoceles may go unrecognized.

Algorithm for our study:

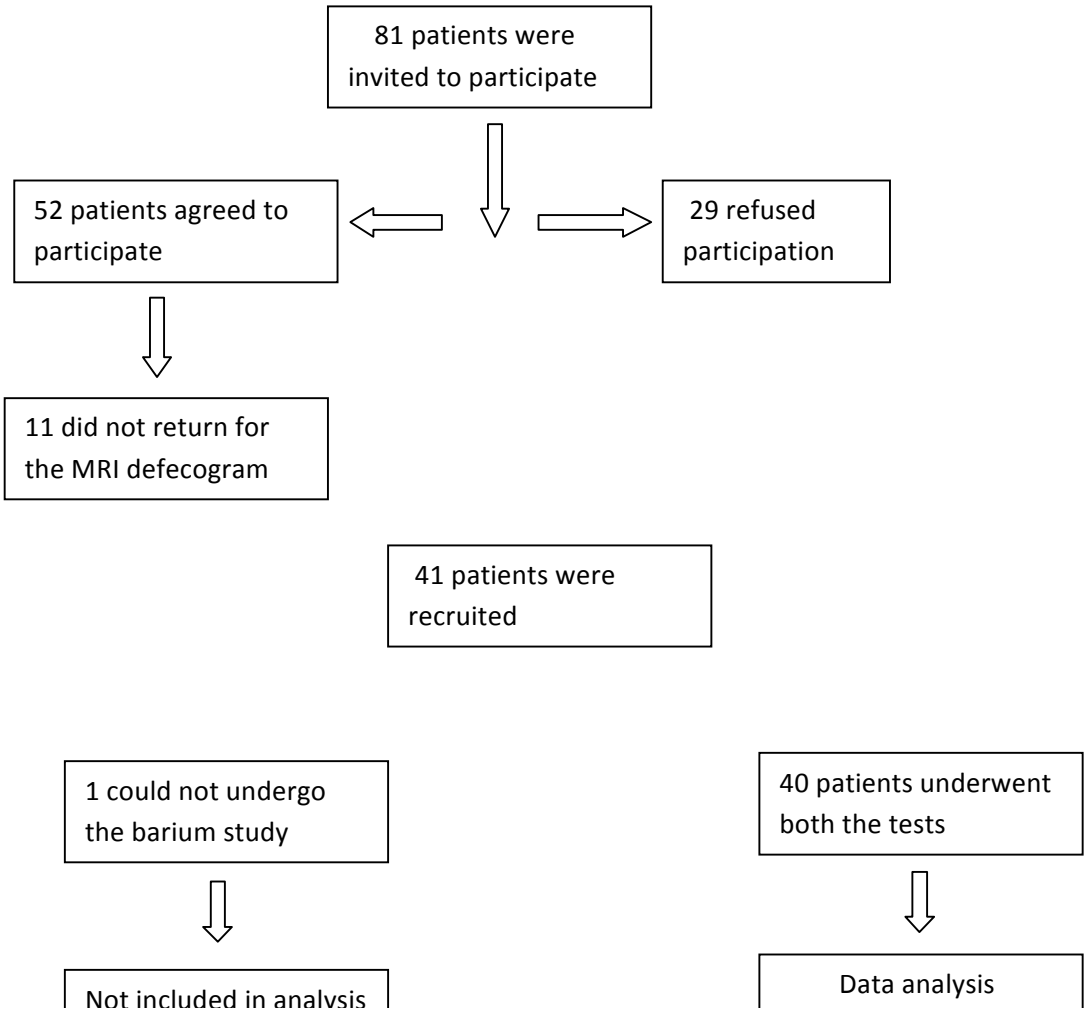


RESULTS:

STUDY PARTICIPANTS:

The study was conducted between November 2014 – August 2016.

81 consecutive patients were invited to participate in the study. These patients were those who were referred for a barium defecogram. Only explaining the procedure, 29 patients did not agree and declined participation in the study. Of the remaining 52 patients who agreed to take part in the study, 11 patients did not show up for the MRI defecogram after the barium study. Finally 41 patients underwent MRI defecography, out of which one was unable to fully complete the barium study, so was excluded from the analysis.



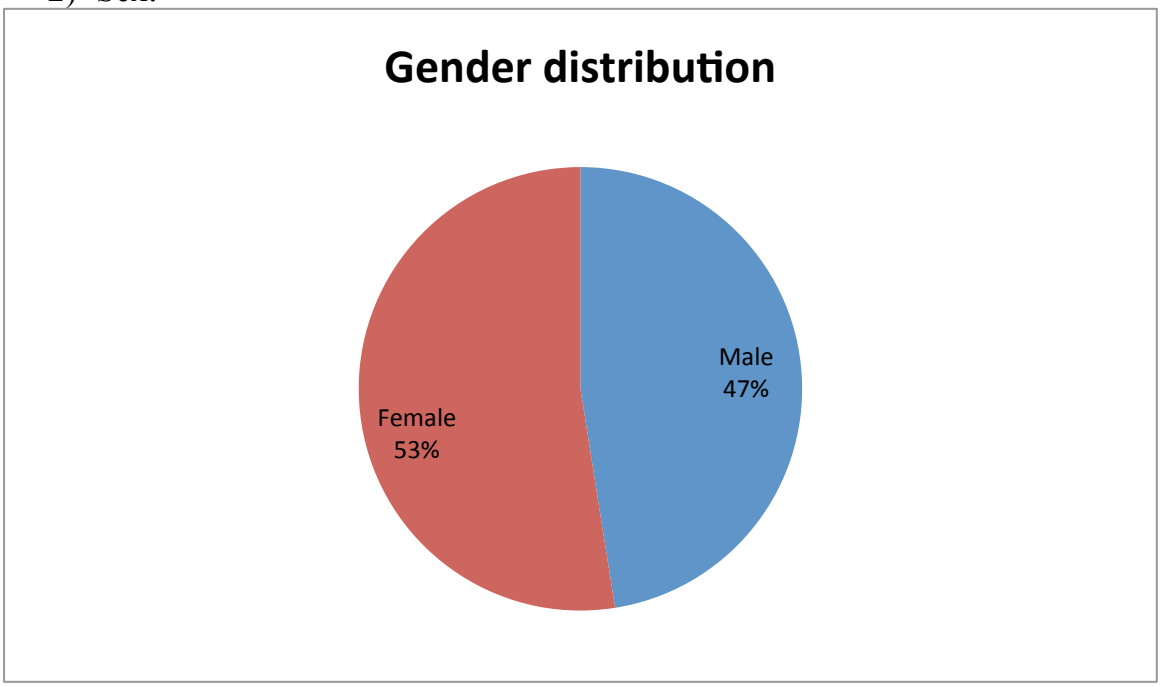
A) Demographic data:

1) Age:

The mean age of the patients included in the study was 43.65, SD- 14.2

(maximum age – 75, minimum age – 21)

2) Sex:

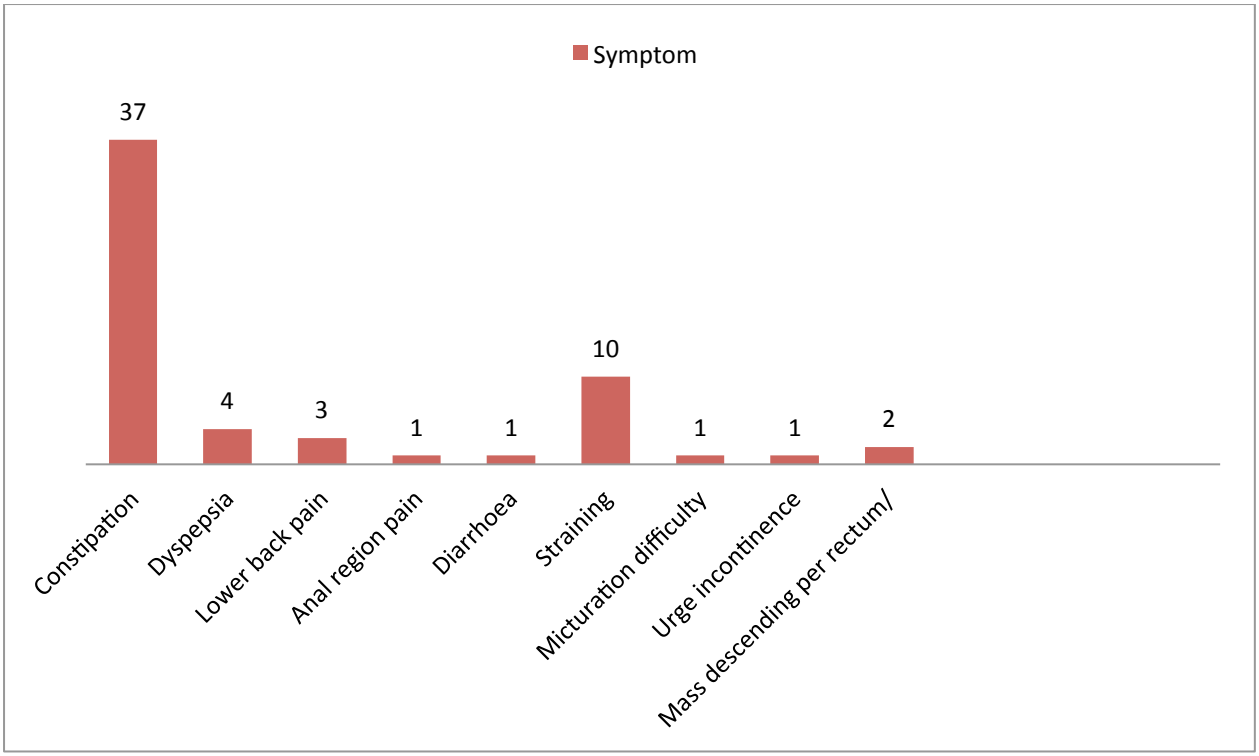


(Figure 23)

21 – female, 19 - male.

3) Symptoms:

The predominant symptom the patients presented with was constipation.



(Figure 24)

B) PROCEDURE AND PATIENT SATISFACTION:

Table 1: comparing the patient's perception of the MRI and barium study:

Questions	Barium	MRI	Chi square value, P value
Contrast instillation 1) Comfortable 2)Uncomfortable	 28 (70%) 12 (30%)	 31 (77.5%) 9 (22.5%)	0.581, 0.446
Holding rectal contrast 1)Easy 2) Difficult	 32 (80 %) 8 (20%)	 39 (97.5%) 1 (2.5 %)	6.135,0.013
Rectal evacuation 1)Easy 2)Difficult	 37 (92.5 %) 3 (7.5 %)	 26 (65 %) 14 (35 %)	9.038,0.003
Following instructions			2.051,0.152

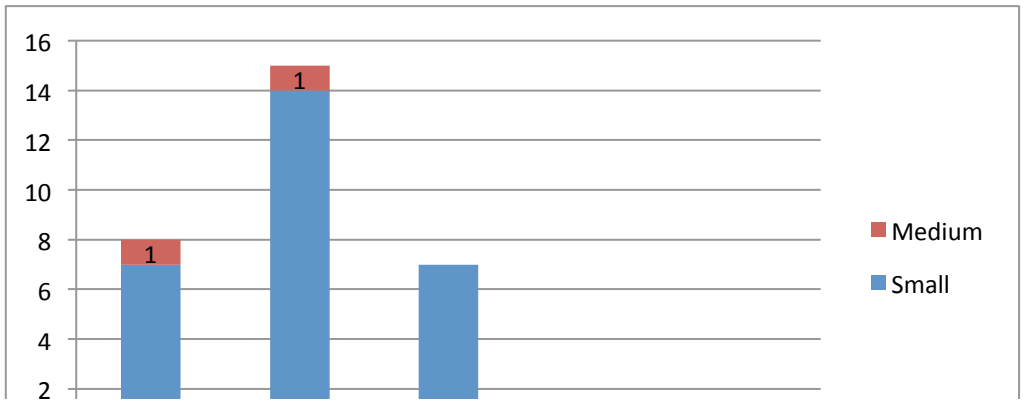
1)Able to follow 2)Unable to follow	40 (100 %) 0	38 (95 %) 2 (5 %)	
Embarrassment	Mean+ 2SD 6.57+-1.5	Mean +2SD 2 +-0.9	DF- 78 P value – <0.001, T value-16.52

- While significant more number of patients perceived difficulty in holding rectal contrast in barium proctography when compared to MR proctography (p-value = 0.013), rectal evacuation was significantly more difficult with MR study compared to the barium (p-value=0.003).
- Patient's perceived more embarrassment with barium proctography when compared to MR proctography which was noted as higher mean embarrassment score in the former compared to later (p-value =<0.001)
- There was no statistically significant difference between barium and MR procedures in the ease of contrast instillation and patients following instructions.

C) BARIUM DEFEOCOGRAM VS MRI DEFECOGRAM:

FINDINGS :

1) Rectocele:

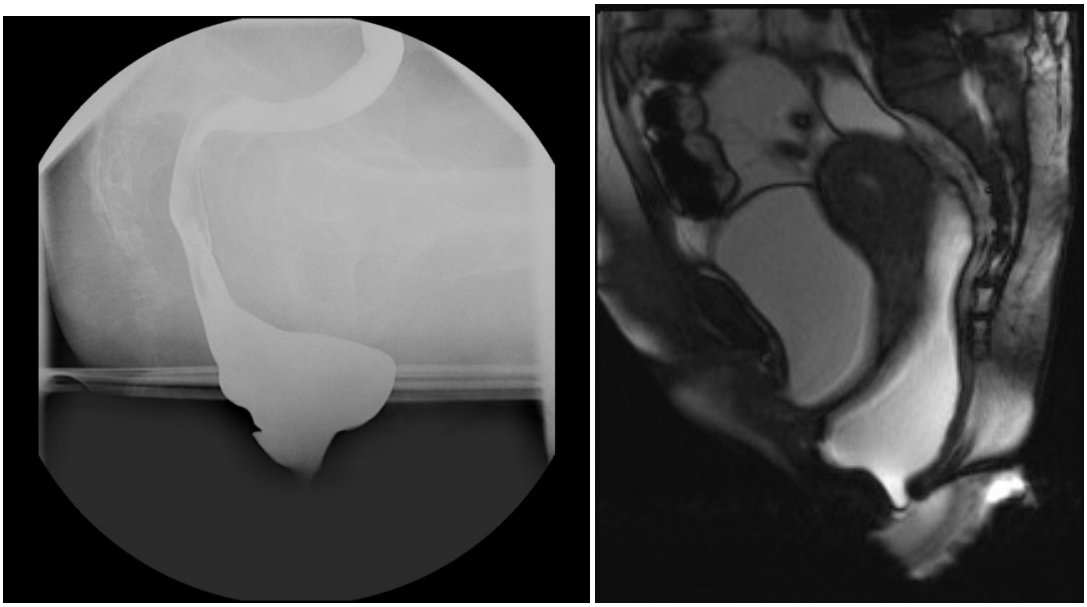


(Figure 25)

8 rectoceles were picked up on barium defecogram(20 %), out of which 7 were small and 1 was medium.

15 rectoceles were picked up on MRI(37.5%), out of which 14 were small and 1 was medium.

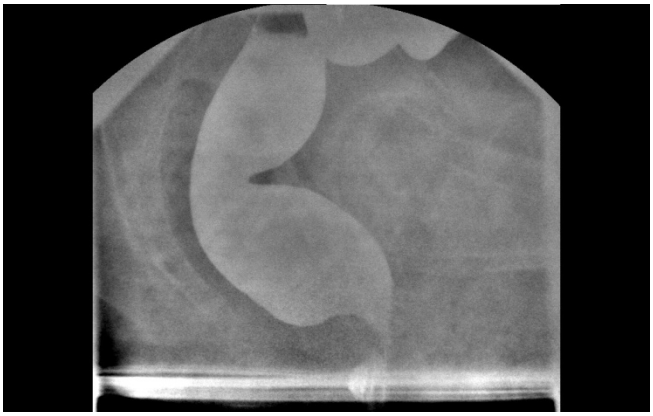
. All the 7 small rectoceles reported on barium were also reported on the MRI.



(Figure 26 - s*mall anterior rectocele demonstrated on both the MRI and barium studies in a patient in our study)*

2) Anismus:

One case of anismus was reported on barium while no cases were reported on MRI



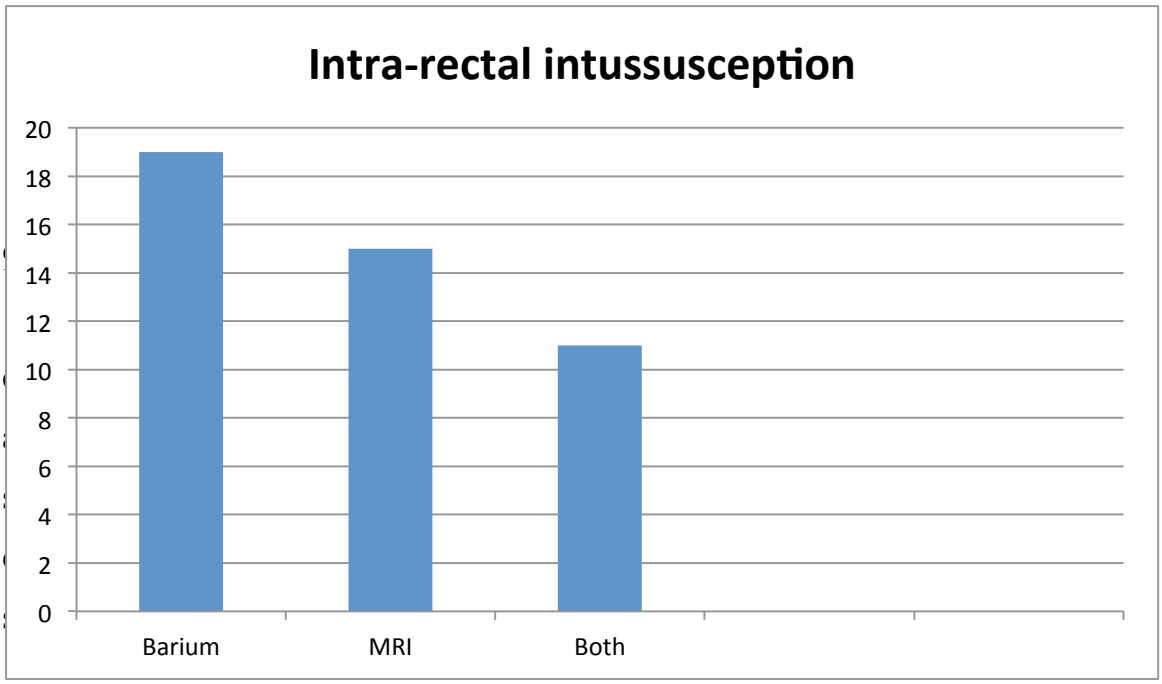
Prominent puborectalis impression seen in a patient on the barium defecogram

(Figure 27)

3) Intra-rectal intussusception:

ntra-rectal

(Figure 28)



(47.5 %) were reported on barium while 15 cases(37.5 %) were reported on MRI.

11 cases (27.5 %) were reported on both the studies.

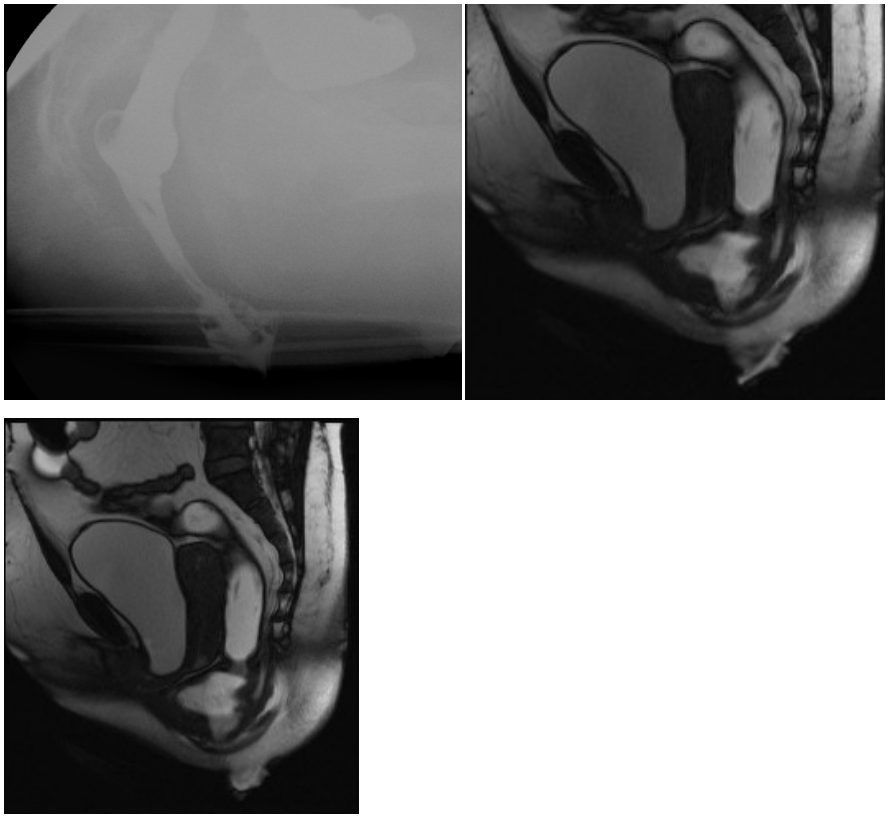


Figure 29 - Intra-rectal intussusception seen on the barium defecogram and MRI defecogram of one of the participants

4)Rectal prolapse:

Two cases (5%)were reported on barium and none on MRI.

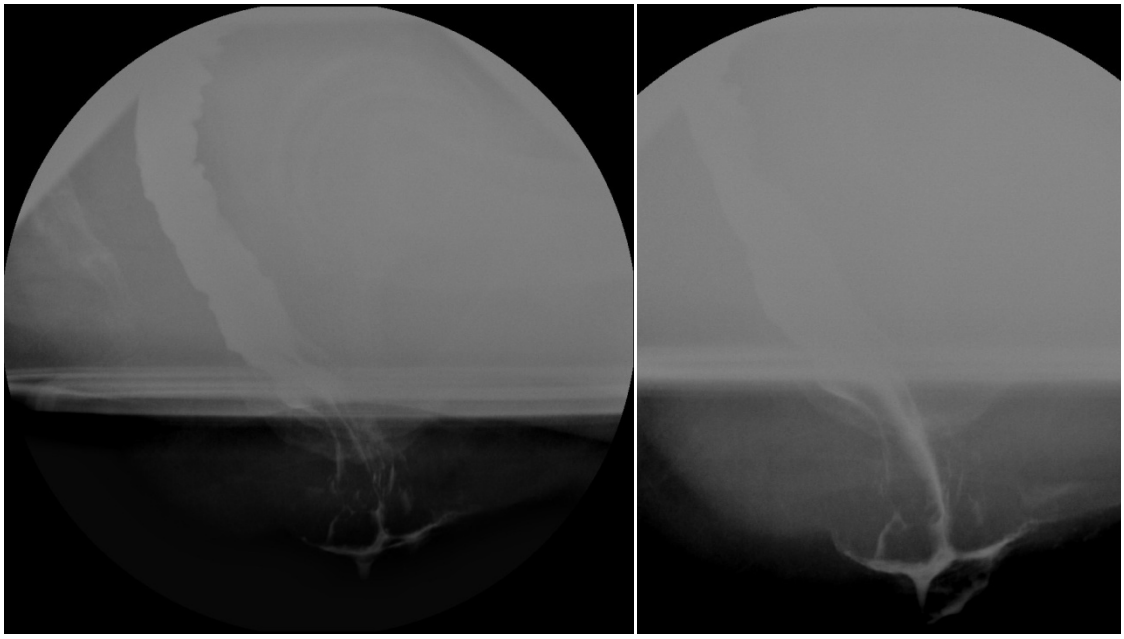


Figure 30 - Barium defecography showing rectal prolapse

5) Intra-anal intussusception:

   3 cases(7.5%) were reported on barium and none on MRI.

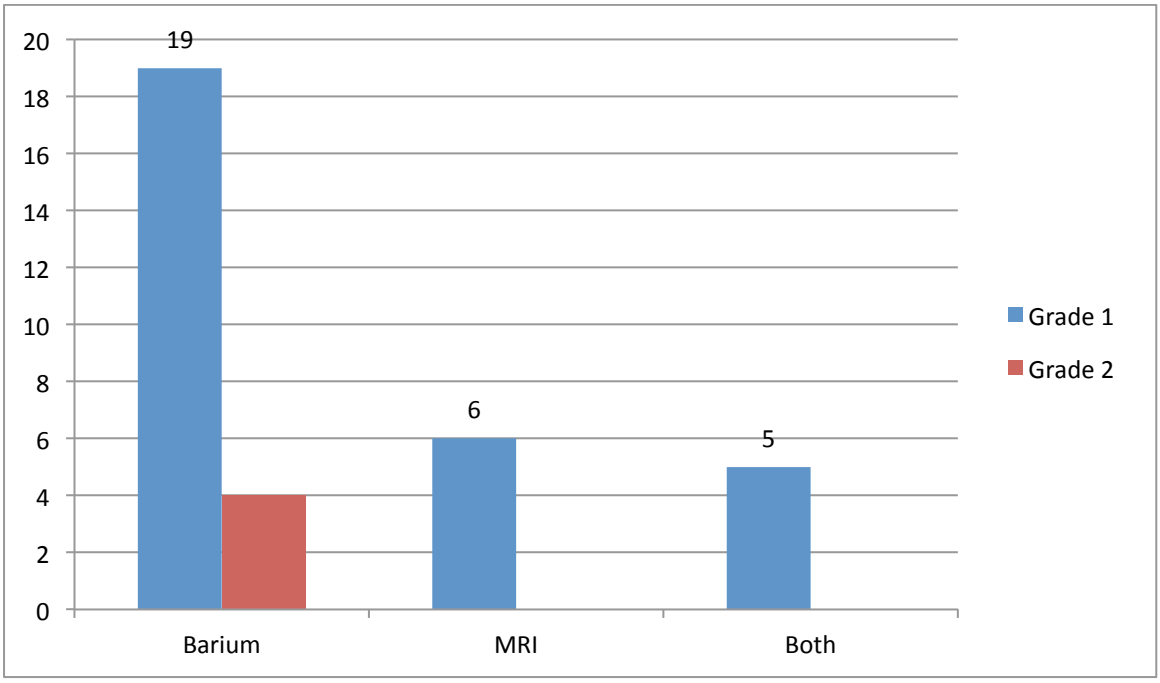
6) Rectal voiding:

All patient's were reported to have complete rectal voiding

7) Contrast trapping:

   One case(2.5%) of contrast trapping was reported on barium, which was less than 30 %. No cases of contrast trapping were reported on MRI.

8) Pelvic cavity widening:



(Figure 31)

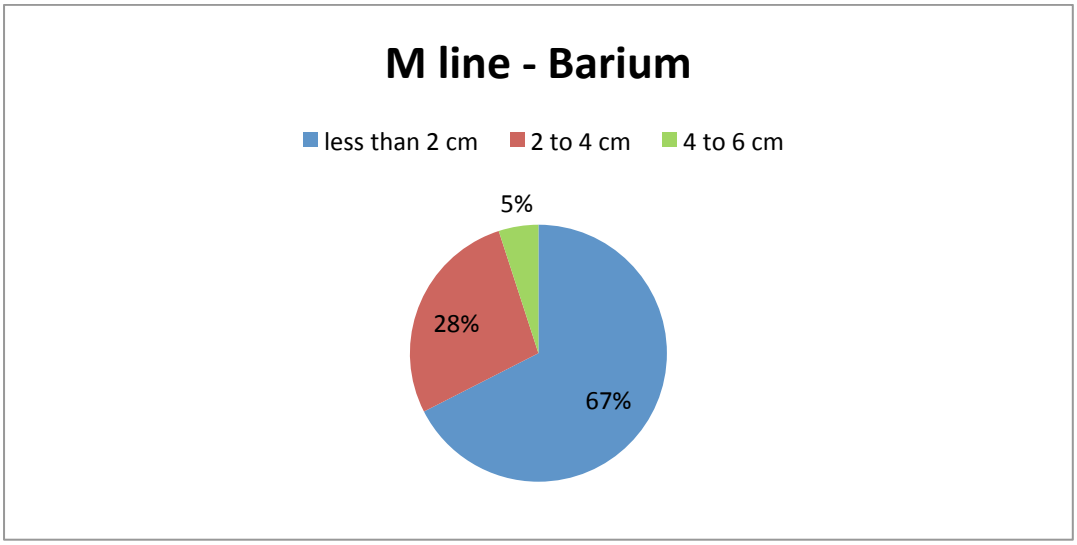
23 cases(57.5%) of pelvic cavity widening were reported on barium out of which 19(83%) were grade 1 and 4 (17%)were grade 2.

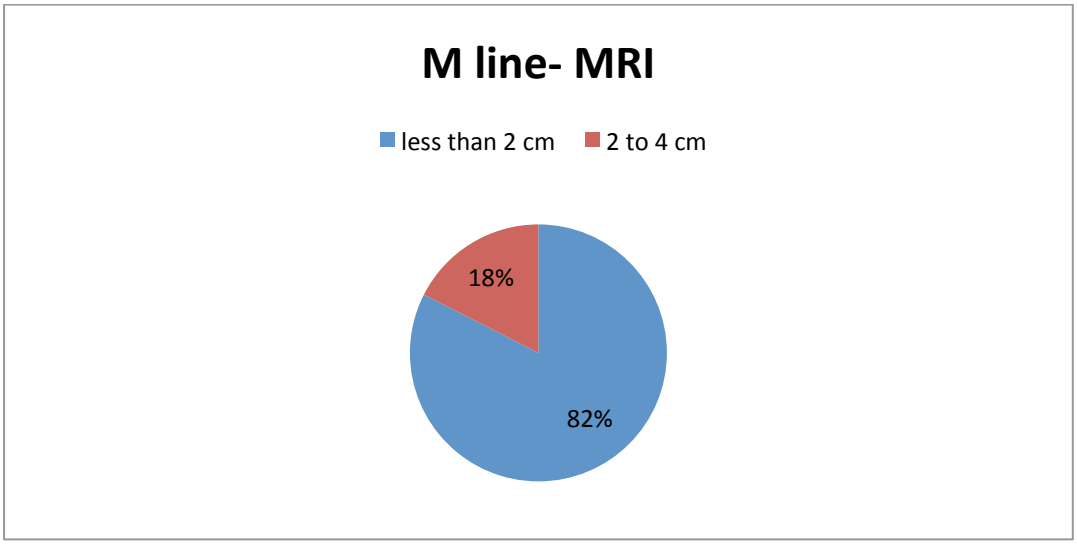
All 6 cases(15%) reported on MRI were grade I.

Only 5 cases(12.5%) were reported on both studies, all of which were grade 1. The measure of agreement was 0.140 which was poor.

Mean pelvic cavity width on barium was 6.27 and on MRI was 5.1.

9) M line:





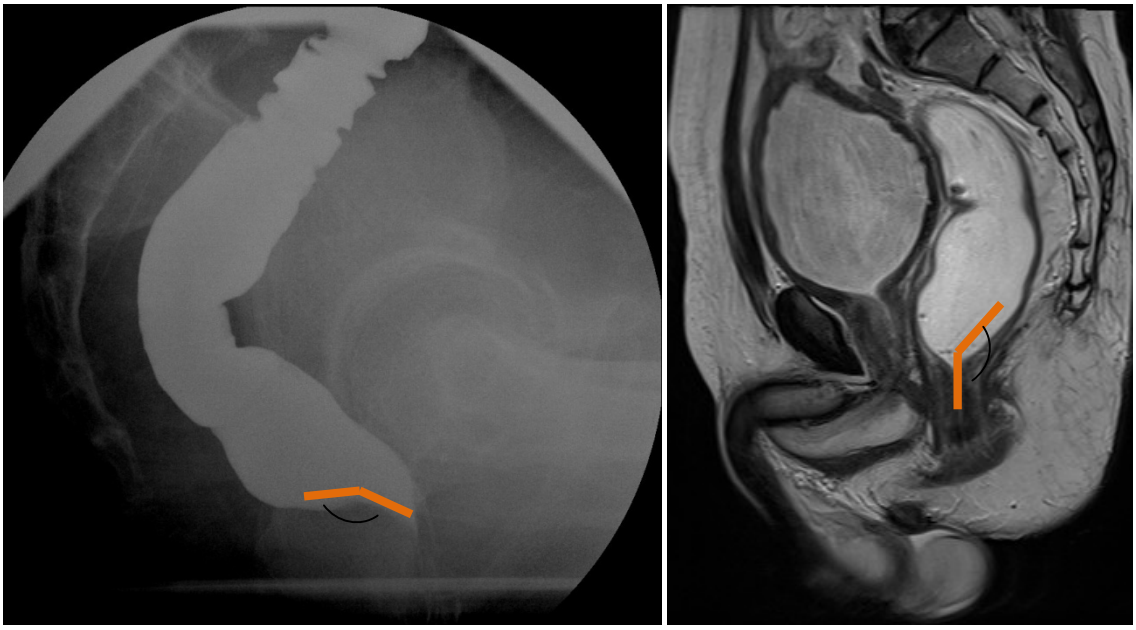
(Figure 32)

On the MRI study, 33 cases were reported as less than 2 cm and 7 cases were 2-4 cm.

On the barium study, 27 cases were reported as less than 2 cm, 11 cases as 2-4 cm and 2 cases as 4-6 cm.

24 cases were reported on both studies as less than 2 cm and 3 cases(7.5%) were reported on both as 2 to 4 cm.

10) Anorectal angle :



(Figure 33 - Anorectal angles on barium and MRI)

The mean angles reported were the following:

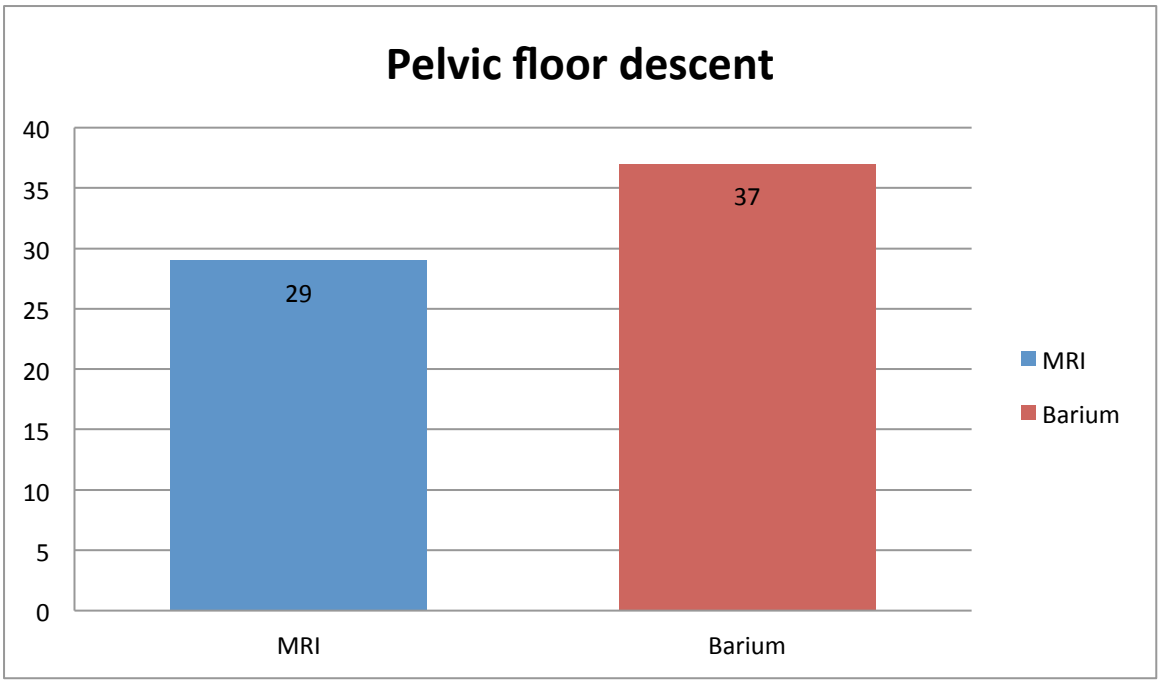
On barium:

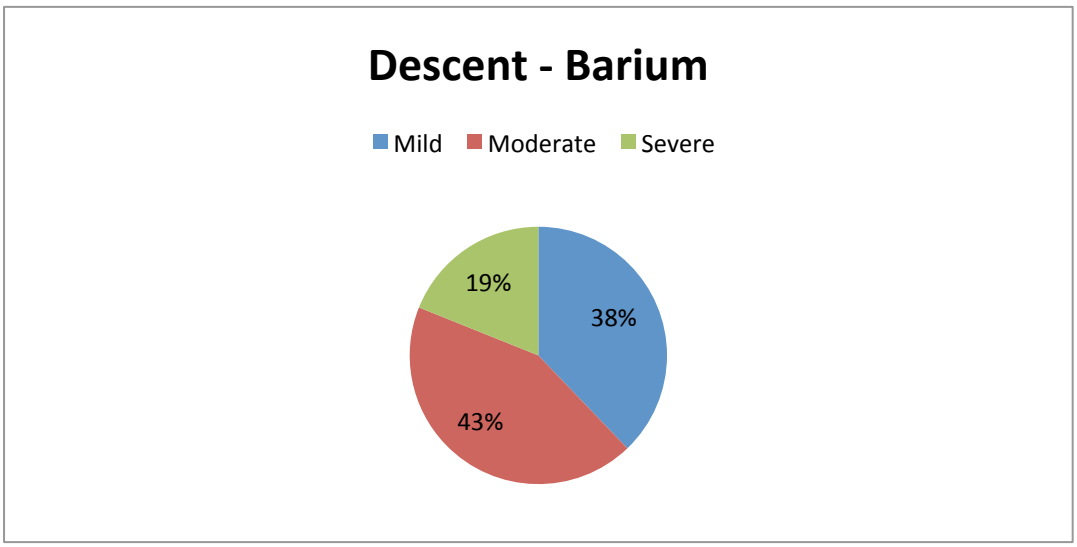
1. Rest – 111.45, SD – 14.8 (CI :99.2-125.2)
2. Squeeze – 110.75 , SD – 15.1 (CI: 100-120.7)
3. Defecate – 125.9, SD – 14.3 (CI – 120- 135.75)

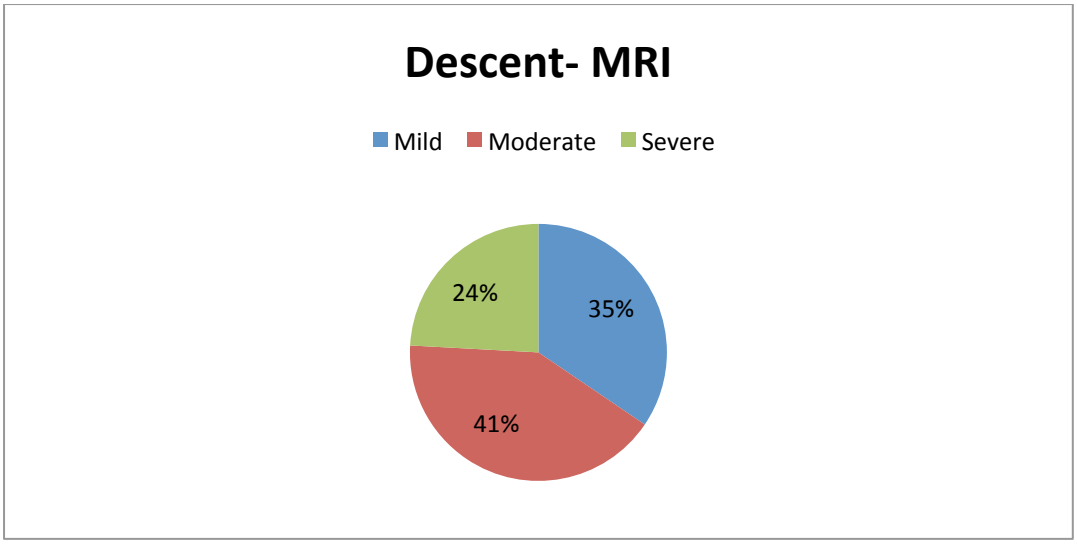
On MRI

1. Rest – 100.87, SD – 13.1 (CI: 91.25 – 108.5)
2. Squeeze – 91.4, SD – 14.7 (CI: 81.25- 101)
3. Defecate – 111.1, SD – 16.6 (CI:101.25- 117.5)

11) Pelvic floor descent and grades:







(Figure 34)

On the MRI, 29 cases (72.5%) of pelvic floor descent were reported, out of which 10 were mild, 12 were moderate and 7 were severe.

On the barium study, 37 cases (92.5%) of pelvic floor descent were reported, out of which 14 were mild, 16 were moderate and 7 were severe.

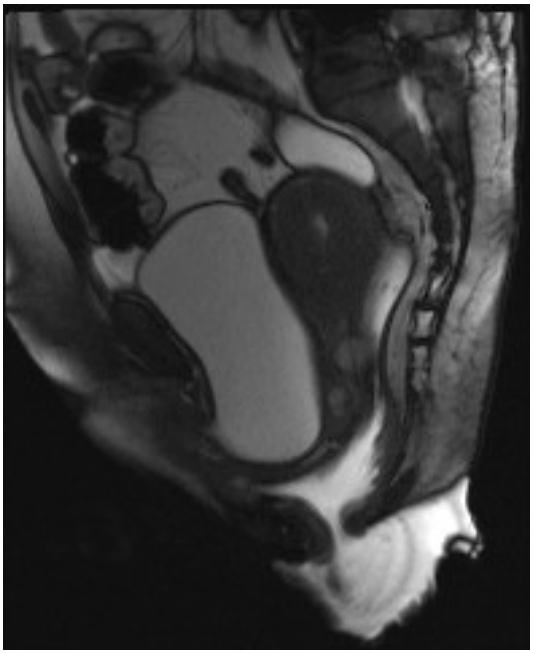


Figure 35- MRI defecography showing severe pelvic floor descent

Table 2: Comparing imaging findings identified on Barium and MR proctography:

SN	FINDINGS	BARIUM (%)	MRI (%)	P value
1.	Rectocele	8 (20%) Small: 7(87.5%) Medium: 1(12.5%)	15 (37.5 %) Small :14(93.3%) Medium:1(6.6%)	0.014
2.	Pelvic cavity widening	23 (57.5%)	6 (15%)	0.165
3.	Pelvic floor descent	37 (92.5%) Mild – 14(38%) Moderate – 16(43%) Severe – 7 (19%)	29 (72.5 %) Mild – 10 (34.5%) Moderate – 12(41.5 Severe – 7 (24%)	0.02
4.	M line - > 2 cm	7 (17.5%) All were 2-4 cm	13 (32.5 %) 2-4 cm-11(85%) 4-6 cm – 2 (15%)	0.125
5.	Intra-rectal intussusception	19 (47.5%)	15 (37.5%)	0.011
6.	Rectal prolapsed	2 (5%)	0	1.0
7.	Intra-anal intussusception	3 (7.5%)	0	1.0
8.	Complete rectal voiding	40 (100%)	40 (100%)	-
9.	Contrast trapping	1 (2.5%)	0	-
10.	Anismus	1 (2.5 %)	0	-

11. Anorectal angle	Mean+2SD Barium	Mean+2SD MRI	P value
Rest	111.45 +– 14.8	100.87 +– 13.1	0.002
Squeeze	110.75 + – 15.1	91.4 +– 14.7	<0.001
Defecation	125.9 + – 14.3	111.1 +– 16.6	<0.001

a) While significantly more number of rectoceles (p value=0.014) were diagnosed on MR proctography, more number of pelvic floor decent (p value=0.02) and

intra-rectal intussusceptions (p value= 0.011) were diagnosed on barium proctography.

b) There were statistically significant differences in the measurement of anorectal angle in all three phases – rest, squeeze and defecation between the two studies.(p values = 0.002, <0.001, <0.001 respectively).

D) INTER-OBSERVER VARIABILITY :

a)BARIUM:

Table 3 showing the agreement between the two observers in interpreting various findings seen in barium proctography. Interobserver agreement displayed as weighted kappa which was interpreted using guidelines of Landis and Koch.

S.NO	FINDING	WEIGHTED KAPPA	P value
1.	Rectocele	0.729	<0.001
	Pelvic cavity widening	0.38	0.16
	Pelvic floor descent	0.46	<0.001
	M line - > 2 cm	0.61	<0.001
	Intra-rectal Intussusceptions	0.119	0.308
	Rectal prolapse	0.655	<0.001
	Intra-anal Intussusceptions	-	
	Complete rectal voiding	-	
	Contrast trapping	-	
	Anismus	0.0	-
11.Anorectal	Mean+ Doctor 1	Mean+2SD Doctor2	Kappa, P value

Angle			
Rest	111.45 +– 14.8	110.5+-13.6	0.446, 0.632
Squeeze	110.75 + – 15.1	100.4+-12.5	0.56, 0.002
Defecation	125.9 + – 14.3	145.7+-18.6	0.575, <0.001

In interpreting barium proctography, the interobserver agreement was substantial for identifying rectocele, rectal prolapse and determining M line.

Inter-observer agreement was moderate for determining anorectal angle and pelvic floor decent.

D) INTER-OBSERVER VARIABILITY:

b) MRI:

Table 4 showing the agreement between the two observers in interpreting various findings seen in MR proctography. Interobserver agreement displayed as weighted kappa which was interpreted using guidelines of Landis and Koch.

S.NO	FINDING	WEIGHTED KAPPA	P value
1.	Rectocele	0.386	0.004
2.	Pelvic cavity widening	0.48	0.16
3.	Pelvic floor descent	0.44	<0.001
4.	M line - > 2 cm	0.61	0.125
5.	Intra-rectal Intussusceptions	0.028	0.766
8.	Incomplete rectal voiding	-	
9.	Contrast trapping	-	
10.	Anismus	0.0	-
11.	Puborectalis thickness	0.65	<0.001
12.	Defect in the puborectalis	0.0	1.0
13.	Cystocele	0.83	<0.001
14.	Urethral descent	0.64	0.00

15.	Urethral funneling	-0.048	0.507
16.	Peritoneocele	1.0	<0.001
17.	Uterine prolapsed	0.85	<0.001
18.	Enterocele	0.0	-

19. Anal canal	Doctor 1	Doctor 2	Kappa, P value
Rest	29.4+– 6.2	25.2+-6.9	0.608 , <0.001
Squeeze	27.3+-7.7	23.5+-6.9	0.838, 0.003
Defecation	17.4+-8	13.3+-6.4	0.78, <0.001

20. AR angle	Doctor 1	Doctor 2	Kappa, P value
Rest	100.87 +– 13.1	105.3+-13.5	0.84, 0.010
Squeeze	91.4 +– 14.7	96.4+-15.3	0.71, <0.001
Defecation	111.1 +– 16.6	127.9+-20.1	0.652, 0.027

- There was excellent inter-observer agreement in interpreting cystoceles, peritoneoceles and uterine prolapse.

- There was substantial to excellent agreement between the observers for determining anal canal length and anorectal angle using MRI.

- There was substantial agreement between the observers for determining the puborectalis thickness and urethral decent.
- There was moderate agreement between the observers for determining the pelvic floor decent.
- Finally, there was fair agreement between both the observers in determining rectoceles.

E) The average time taken for the barium defecogram study was ~ 12 minutes while the MRI study was ~ 15 mins .

DISCUSSION:

Pelvic floor disorders are a commonly occurring health problem especially among women. Childbirth, obesity, previous surgery or strenuous physical activity are few of the predisposing features and can produce symptoms such as fecal and urinary incontinence, constipation, difficulty in voiding, etc. In our institution, Christian Medical College, barium proctography is currently the standard test ordered for patients with pelvic floor disorders. This is a good test to demonstrate disorders of the posterior compartment such as rectal prolapse, rectal intussusception, rectocele, etc. However diseases of the anterior and middle compartment cannot be diagnosed on this test. Even if we have to do so, this involves instilling contrast in the vagina and bladder which are invasive and increases the chance of infection. Barium proctography also involves subjecting the patient to ionizing radiation and can be quite embarrassing for the patients as well.

MRI proctography overcomes certain limitations of the conventional barium proctography as all three compartments, the anterior, middle and posterior compartments can be well visualized without additional instillation of contrast into the anterior and middle compartments and hence many other disorders which may have an impact on the management can be identified. MR proctography also provides good evaluation of the pelvic ligaments, fascia and the function of the anorectal and pelvic muscles. It is free of ionizing radiation and is said to have higher patient compliance.

Our aim is to compare MR and barium proctography in patients with pelvic floor disorders and study their perception of the test. There are very few centers which offer this test in our

country. We aim to introduce this test and make it available for patients at our institution if we manage to establish significant additional benefit.

The study was conducted between November 2014 – August 2016.

81 consecutive patients were invited to participate in the study. These included those patients who were referred for a barium defecogram. Many of the patients wanted to consult with their clinician prior to agreeing the study. Only explaining the procedure, 29 patients did not agree and declined participation in the study. Of the remaining 52 patients who agreed to take part in the study, 11 patients did not turn up for the MRI defecogram after the barium study. Finally 41 patients underwent MRI defecography, out of which one was unable to fully complete the barium study, so was excluded from the analysis.

Patient perception and procedure:

Significantly more number of patients perceived difficulty in holding rectal contrast in barium proctography when compared to MR proctography (p-value = 0.013). However rectal evacuation was found to be more difficult with MR study compared to the barium (p-value=0.003). This could be attributed to the supine position of the study as compared to the normal physiological position of defecation on the barium proctography.

These results were in keeping with the studies described previously which also found rectal evacuation more difficult on the MR study than on the barium, likely due to the non-physiological position.(24)

Patient's reported more embarrassment with barium proctography when compared to MR proctography with a higher mean embarrassment score noted on the barium proctography study as compared to the MRI (p-value =<0.001)

These results were also in keeping with the previously described studies.(24)

Findings on the MR proctography as compared to barium proctography:

While significantly more number of rectoceles (p value=0.014) were diagnosed on MR proctography, more number of pelvic floor decent (p value=0.02) and intra-rectal intussusceptions (p value= 0.011) were diagnosed on barium proctography. Probably more rectoceles were seen on MRI due to better spatial resolution of MRI.

On the other hand, the reason for more number of pelvic floor decent (p value=0.02) and intra-rectal intussusceptions (p value= 0.011) being diagnosed on barium proctography, may be due to the more physiological position of the patient.

There were statistically significant differences in the measurement of anorectal angle in all three phases – rest, squeeze and defecation between the two studies.(p values = 0.002, <0.001, <0.001 respectively). However, this is less relevant clinically and the differences again may be due to inherent differences in the patient's position and the resolution of the imaging modalities.

The detection of rectoceles was in contrast to previous studies which reported a substantial to good agreement between both the tests in the detection of rectoceles (k-0.690)(24). The previous studies reported a clinically significant difference in the size of the rectoceles(21),(24). However the results were similar to one previous study which found the sensitivity and specificity of detecting rectoceles on MR colplocystorectography (69% and 96 % respectively) was slightly higher than barium proctography (50% and 93% respectively)(22).

The increased detection of intra-rectal intussusceptions on barium proctography has also been described in previous studies where they found that MR proctography missed ~ 31 % of cases detected on the barium proctography (24)and the measure of agreement between both the tests for this parameter was found to be fair(k-0.209)(24). This was assumed to be contributed by the fact that in many of the cases there was a failure of rectal evacuation on the MR study. In previous studies, there has also been a significant difference in the detection of rectal prolapse between conventional and MR defecography. (38)

Inter-observer variability:

In interpreting barium proctography, the interobserver agreement was substantial for identifying rectoceles(k-0.729, p value- <0.001), rectal prolapse(k-0.655, p value<0.001) and determining the M line(k-0.61, p- <0.001) and was moderate for determining the anorectal angle(k- 0.44 to 0.57) and pelvic floor decent(k-0.46, p value -<0.001)

In interpreting MRI proctography, there was excellent inter-observer agreement in interpreting cystoceles(k-0.83, p value- <0.001) peritoneoceles(k -1, p value<0.001) and uterine prolapse(k-0.85, p value-< 0.001) and substantial to excellent agreement between the observers for determining anal canal length (k- 0.6-0.83, p value- <0.001)and ano-rectal angle(k- 0.65-0.84, p value – 0.02 to<0.001) using MRI. There was however only a fair agreement between both the observers in determining rectoceles.(k-0.38, p value – 0.004)

Weighted kappa was used for comparing the inter-observer variability as kappa does not take into account the degree of disagreement between the observers and all disagreement is treated equally as total disagreement. Thus as there were various categories to be analysed , it was preferable to use weighted kappa so that different levels of agreement contributed to the value of Kappa as we were more interested in the agreement across the major categories in which there was a meaningful difference.

LIMITATIONS:

1) Making comparisons of studies performed in different positions.

2) More symptomatic patients may not have consented and this may have introduced bias in the findings.

3) There were more surgical referrals than gynecology referrals making studying the middle and anterior compartment less contributory in the study group while it may not be so if referrals were from pelvic floor clinic.

CONCLUSION:

1. Assessment of the anterior and middle compartment in addition to the posterior compartment gives MRI proctography an added advantage over barium proctography.

2. In our study, MRI proctography findings were comparable to barium proctography in the assessment of pelvic floor disorders and MRI proves to be a valuable imaging modality that does not involve the risk of radiation. However in patients with predominantly posterior compartment symptoms, barium proctography may be adequate for diagnosis.

3. Patient's perceived much less embarrassment with MRI proctography when compared to barium proctography, however rectal evacuation was significantly more difficult with the supine MR study compared to the barium study.

4. There was good to substantial inter-observer agreement in the assessment for most parameters on both the studies.

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ANNEXURES:

Appendix 1

ABSTRACT:

TITLE:

Comparison of MR proctography and barium proctography in patients with pelvic floor disorders

AIMS AND OBJECTIVES:

1) To compare imaging features of patients with pelvic floor disorders seen in MR defecogram and barium defecogram

2) To assess patient perception of these procedures

MATERIALS AND METHODS:

This was a prospective study approved by the institutional review board (IRB NO :9135).Consecutive patients with pelvic floor disorders who underwent barium proctography were included in the study. All the participants underwent both the barium and the MRI proctography in our institution and interpreted by two radiologists who were blinded to the results of the other procedure. Following both the test, the patients were provided with a questionnaire containing 5 questions which assessed their perception of the test.

RESULTS:

Forty patients (M:F = 19:21) and mean age of 43.65(+/- 2SD) and range of 21-75 years underwent both barium and MR procography. Patient's perceived more embarrassment with barium proctography when compared to MR proctography which was noted as higher mean embarrassment score in the former compared to later (mean score in barium(6.5) vs MRI (2), p-value = <0.001). However, more number of patients perceived difficulty in rectal evacuation with the MR study compared to the barium (p-value=0.003). While significantly more number of rectoceles (p value=0.014) were diagnosed on MR proctography, more number of pelvic floor decent (p value=0.02) and intra-rectal intussusceptions (p value= 0.011) were diagnosed on barium proctography. The inter-observer variability for the barium proctography was substantial for identifying rectoceles, rectal prolapse and for determining the M line (p values< 0.001). The inter-observer variability for the MRI proctography was excellent in interpreting cystoceles, peritoneoceles and uterine

prolapse and substantial to excellent for determining anal canal length and ano-rectal angle.(p values < 0.001). The mean time in minutes for the barium study was 12 minutes while for the MRI study was 15 minutes.

CONCLUSION:

MRI proctography findings were comparable to barium proctography in the assessment of pelvic floor disorders and proves to be a valuable imaging modality that does not involve the risk of radiation. However in patients with predominantly posterior compartment symptoms, barium proctography may be adequate for diagnosis.

Appendix 2:

INFORMED CONSENT

Christian Medical College, Vellore

Department of RADIOLOGY

An observational study comparing MR defecogram vs Barium defecogram in patients with pelvic floor disorders

Information sheet

You are being requested to participate in a study to see if MR defecography has an added advantage over barium defecography in patients with pelvic floor disorders. There are no added risks with this new test. We hope to include about 40 people from this hospital in this study.

What additional information can be diagnosed on MR defecography?

There are few studies done showing MR defecogram will help diagnose additional disorders that cannot be seen on barium defecogram. This can have a definite impact on your final management and hence may be very useful. This is however a more expensive test. After this study, if results are promising, we can start this investigation on a routine basis. This investigation will be performed free of cost.

Does MR defecogram have any risk factors associated?

MR defecogram does not involve radiation. There are no added risks associated with this test.

What do you have to do if you take part in this study?

If you agree to participate in this study, you will undergo an MR defecogram after your routine barium defecogram, but within your next OPD visit. The results of both the tests will then be compared by the radiologist and the report conveyed to your treating doctor. Based on this report and various other factors he/she will decide your final treatment options.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any procedure related complication.

Will you have to pay for the study ?

No

What happens after the study is over?

The results of the study will be sent to your treating doctor and management planned on findings of both studies put together.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal, but your identity will not be revealed in the publication or presentations made at medical forums. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask Dr.Deepa, Dr.Anuradha or Dr. Anu Eapen (tel: 0416 2283012) or email: radio@cmcvellore.ac.in

CONSENT FORM:

Study Title: MR defecogram vs Barium defecogram in patients with pelvic floor disorders

Study Number:

Participant's name:

Sex:

Date of Birth / Age (in years):

Hospital number:

I_____

_____, son/daughter of _____

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ )

I understand that I will receive free treatment for any study related injury or adverse event but I will not receive any other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name:

Signature/ Thumbprint:

Place

Date:

Name of witness:

Signature/ Thumbprint:

Relation to participant:

Place

Date:

Appendix 3

Performa: Barium vs MR defecogram

Name: _____

Hospital number:_____

Age: _____years Sex: Male – 1; female - 0

	Barium defecogram	**MR defecogram**
Puborectalis thickness and signal intensity (coronal and axial)	NA	Normal – 0 Abnormal – 1
Defect in the puborectalis (coronal)	NA	Yes-1 No-0
Levator hiatus (cm)	NA	
Pelvic cavity widening assessed using H line (line from inferior aspect of SP to posterior rectal wall just above A-R Jn	Yes-1 No – 0	Yes-1 No – 0
Pelvic cavity width (H line in cm)		
Pelvic cavity widening if yes	Mild (>6-8 cm) – 1 Moderate (8-10 cm) – 2 Severe (>10 cm) - 3	Mild (>6-8 cm) – 1 Moderate (8-10 cm) – 2 Severe (>10 cm) – 3
M line (length of perpendicular from Pubococcygeal line to H line) – indicates levatorani strength and normal <2 cm	2-4 cm – 1 4-6 cm – 2 >6 cm – 3	2-4 cm – 1 4-6 cm – 2 >6 cm – 3
Urethral descent / hypermobility (when urethra/ neck of bladder decents below the level of symphysis pubis during straining/ defecation)	NA	Yes – 1 No- 0
Cystocele	NA	Yes-1 No-0
If there is cystocele		<3 cm – small – 1 3-6 cm – moderate – 2 >6 cm – large – 3
Pudocervical fascia/ ligament – rotation of urethra/ vagina assessed by deviation of these structures from the line drawn from the SP to coccyx)	NA	Yes – 1 No- 0

Funnelling of proximal urethra/ opening of the urethra-vesicaljn	NA	Yes-1 No-0
Uterine prolapsed	NA	Yes-1 No-0
If uterine prolapse is present Descent of cervico-uterine junction/ vault in hysteretomy>2 cm below the pubococcygeal line	NA	Mild - <3 cm – 1 Moderate – 3-6 cm – 2 Severe - >6 cm – 3
Peritoneocele (inferior herniation of peritoneal pouch along the anterior rectal wall)	NA	Mild – till lower third of vagina -1 Mod – till perineum – 2 Severe – beyond anal canal – 3
Enterocele	NA	Yes-1 No-0
Sigmoidocele	NA	Yes-1 No-0
Ano-rectal angle: (degrees) Normal: rest – 70-135; squeeze – decreases; defecation – increase > 20 deg from rest	Rest: Squeeze: Defecation:	Rest: Squeeze: Defecation:
Anal canal length: (cm)	Rest: Squeeze: Defecation:	Rest: Squeeze: Defecation:
Ano-rectal junction from pubococcygeal line – pelvic floor descent	<2 cm – 0 2-4 cm – mild - 1 4-6 cm – mod – 2 >6 cm – severe - 3	<2 cm – 0 2-4 cm – mild - 1 4-6 cm – mod – 2 >6 cm – severe – 3
Rectocele	<2 cm -0 Small – 2-4 cm – 1 Medium–4-6 cm – 2 Large - > 6 cm - 3	<2 cm -0 Small – 2-4 cm – 1 Medium – 4-6 cm – 2 Large - > 6 cm – 3
Contrast trapping in the rectocele	Yes – 1 No – 0	Yes – 1 No – 0
If yes	>30% - 1 < 30% - 0	>30% - 1 < 30% - 0
Anismus or spastic pelvic floor syndrome Paradoxical puborectalis contraction at defecation seen as prominent posterior puborectalis indentation or ano-rectal angle fails to become obtuse during defecation	Yes – 1 No – 0	Yes – 1 No – 0
Intra-rectal intussusceptions	Yes-1 No-0	Yes – 1 No – 0

Intra-anal intussusceptions	Yes – 1 No-0	Yes – 1 No-0
Rectal prolapsed	Yes – 1 No-0	Yes – 1 No-0
Degree of rectal voiding	Incomplete – 1 Complete – 0	Incomplete – 1 Complete – 0
Anal sphincter complex (signal intensity and thickness)		Abnormal – 1 Normal – 0
Other significant pathology (write what)		
Patient Questionnaire		
Instillation of rectal contrast	Uncomfortable – 1 Comfortable – 0	Uncomfortable – 1 Comfortable – 1
Procedure was Not embarrassing to embarrassing (VAS 1 to 10)		
Holding the rectal contrast	Difficult – 1 Easy – 0	Difficult – 1 Easy – 0
Rectal evacuation	Difficult – 1 Easy – 0	Difficult – 1 Easy – 0
Could easily follow instructions	Yes-1 No-0	Yes-1 No-0
Duration of procedure (minutes)		

Patient questionaire:

Kindly give your feedback about the procedure:

1. Was the instillation of rectal contrast - a) comfortable b) uncomfortable
2. On a scale of 1-10, how embarrassing was the procedure?
3. Was it easy or difficult to hold the contrast in?
4. Was rectal evacuation easy or difficult?
5. Were you able to follow the instructions easily? Yes/ No

Appendix 4

ABBREVIATIONS:

MRI: magnetic resonance imaging

CT: computed tomography

USG: ultrasound

mSv: millisievert

IRB: Institutional Review Board

TE: Echo Time

TR: Repetition Time

FSE: fast spin echo

HR: high resolution

FOV: field of view

FIESTA: fast imaging employing steady-state acquisition

T – Tesla

DF – degree of freedom

NEX – number of excitations

The terms proctography and defecography have been used interchangeably.

Appendix 5:

DATA ENTRY SHEETS:

id	age	sex	gende	b_contras	m_contras	b_embarr	m_embarr	b_holding	m_holding	b_rectalev	m_rectale	b_instruct	m_instruc	b_otherco	m_othercomments
1	29	1		0	0	3	3	0	0	0	0	1	1		
2	53	0		0	0	7	2	0	0	0	0	1	1		found barium cumbersome
3	73	1		0	0	8	2	0	0	0	0	1	1		contrast injected into rectum was less
4	35	0		0	0	9	1	0	0	0	1	1	1		
5	34	1		1	1	3	3	0	0	0	1	1	1		
6	40	0		0	0	7	2	0	0	0	0	1	1		
7	29	1		1	1	5	1	0	0	0	0	1	1		
8	54	1		1	1	6	2	0	0	0	1	1	1		
9	44	0		0	0	5	2	0	0	0	0	1	1		
10	27	1		0	0	7	2	1	0	0	0	1	1		
11	23	0		1	1	7	1	1	0	0	0	1	1		
12	56	0		0	0	5	3	0	0	0	0	1	1		
13	31	0		0	0	7	1	1	0	0	0	1	1		
14	23	1		0	0	6	1	1	0	0	0	1	1		
15	64	0		0	0	5	2	0	0	0	1	1	1		
16	47	0		1	1	6	2	0	0	0	1	1	1		
17	44	0		0	0	8	1	0	0	0	0	1	1		
18	62	1		1	0	8	1	0	0	0	0	1	1		
19	30	1		1	0	7	1	1	0	0	0	1	1		
20	44	0		0	0	8	2	1	0	0	0	1	1		
21	49	1		0	0	8	2	0	0	0	0	1	1		
22	41	1		1	1	6	3	0	0	0	1	1	1		
23	42	0		0	0	5	2	0	0	0	0	1	1		
24	29	1		0	0	8	1	0	0	0	0	1	1		
25	29	1		0	0	6	2	0	0	0	1	1	1		
26	61	0		0	0	8	3	0	0	0	1	1	0		
27	50	0		0	0	8	2	0	0	0	0	1	1		
28	57	0		1	1	9	3	0	0	0	1	1	1		
29	32	0		0	0	8	3	0	0	1	1	1	0		
30	56	1		0	0	3	3	1	1	1	1	1	1		
31	69	1		0	0	6	1	0	0	0	0	1	1		
32	34	1		0	0	7	2	0	0	0	0	1	1		
33	38	1		0	0	6	3	0	0	0	1	1	1		
34	38	0		0	0	8	2	1	0	0	0	1	1		
35	75	1		1	1	5	5	0	0	0	0	1	1		
36	21	1		0	0	8	2	0	0	0	0	1	1		
37	40	0		1	0	7	1	0	0	0	0	1	1		
38	41	1		0	0	7	3	0	0	0	1	1	1		
39	60	0		1	1	5	1	0	0	0	0	1	1		
40	41	0		0	0	8	3	0	0	1	1	1	1		

id	age	genger	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_	m_obs2_	m_obs1_
1	29	1	0	0	0	0	4	4.7	0	0	.	.	0	0	0	0	0	0	.
2	53	0	0	0	0	0	6.2	6.7	1	1	1	1	0	0	0	0	0	1	.
3	73	1	0	0	0	0	6.2	5.8	1	0	1	.	0	0	0	0	0	0	.
4	35	0	0	0	0	0	5.3	5	0	0	.	.	0	0	1	1	1	1	1
5	34	1	0	0	0	0	4.8	5.4	0	0	.	.	0	0	0	0	0	0	.
6	40	0	0	0	0	0	4.9	5.2	0	0	.	.	0	0	0	0	0	0	.
7	29	1	0	0	0	0	3.6	4.1	0	0	.	.	0	0	0	0	0	0	.
8	54	1	0	0	0	0	4.6	5	0	0	.	.	0	0	0	0	0	0	.
9	44	0	0	0	0	0	5.7	5.8	0	0	.	.	0	0	0	1	1	1	2
10	27	0	0	0	0	0	4.4	4.4	0	0	.	.	0	0	0	0	0	0	.
11	23	0	0	0	0	0	4.1	5	0	0	.	.	0	0	1	0	1	1	2
12	56	0	1	1	0	1	6	5.2	1	0	1	.	0	2	1	1	1	1	2
13	31	0	0	0	0	0	5.4	6.3	0	1	.	1	1	0	0	0	0	0	.
14	23	1	0	0	0	0	5.8	7.3	0	1	.	1	0	0	0	0	0	0	.
15	64	0	0	0	0	0	4.8	5.8	0	0	.	.	0	0	1	0	1	0	1
16	47	0	0	0	0	0	4.7	5.3	0	0	.	.	0	0	1	1	1	1	2
17	44	0	0	0	0	0	5	6.3	0	1	.	1	1	0	0	0	0	0	.
18	62	1	0	0	0	0	5.7	5.5	0	0	.	.	0	0	0	0	0	0	.
19	30	1	0	0	0	0	3.4	3.3	0	0	.	.	0	0	0	0	0	0	.
20	45	0	0	0	0	0	5.7	7	0	1	.	1	0	0	1	0	1	1	1
21	49	1	0	0	0	0	4.8	4.6	0	0	.	.	0	0	0	0	0	0	.
22	41	1	0	0	0	1	6	6.9	1	1	1	1	1	0	0	0	0	0	.
23	42	0	0	1	0	0	5.5	5.5	0	0	.	.	0	0	0	0	0	0	.
24	29	1	0	0	0	0	5.8	5.9	0	0	.	.	0	0	0	0	0	0	.
25	29	1	0	0	0	0	4	41	0	0	.	.	0	0	0	0	0	0	.
26	61	0	0	0	0	1	5	5	0	0	.	.	0	0	0	0	0	0	.
27	50	0	0	0	0	0	6	6.1	1	1	1	1	1	0	1	1	1	1	2
28	57	0	0	0	0	0	6.2	6.6	1	1	1	1	0	0	1	1	1	1	1
29	32	0	0	0	0	0	5.8	59	0	0	.	.	1	0	0	1	0	1	.
30	56	1	0	0	0	0	4.3	50	0	0	.	.	0	0	0	1	0	0	.
31	69	1	0	0	0	0	5.5	54	0	0	.	.	0	0	0	0	0	0	.
32	34	1	0	0	0	0	5	5	0	0	.	.	0	0	0	0	0	0	.
33	38	1	0	0	0	0	4.9	4.6	0	0	.	.	0	0	0	0	0	0	.
34	38	0	0	0	0	0	5.2	5.2	0	0	.	.	0	0	1	1	1	1	1
35	75	1	0	0	0	0	5.1	5.4	0	0	.	.	0	0	0	0	0	0	.
36	21	1	0	0	0	0	4.5	43	0	0	.	.	0	0	0	0	0	0	.
37	40	0	0	0	0	0	4.9	5.3	0	0	.	.	1	0	1	1	1	1	2
38	41	1	0	0	0	0	4.1	4.7	0	0	.	.	0	0	0	0	0	0	.
39	60	0	0	0	0	0	5.8	6.1	0	0	.	1	1	1	1	1	1	1	1
40	41	0	0	0	0	0	5.5	5	0	0	.	.	0	0	1	1	1	1	2

m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs2	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	89
1	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	112
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	117
1	0	0	0	0	1	0	1	.	0	0	.	.	0	0	0	0	87
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	84
.	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	107
.	0	.	1	0	2	2	.	.	0	0	.	.	0	0	0	0	100
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	106
2	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	94
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	92
1	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	118
2	0	1	0	1	0	0	.	.	0	0	.	.	0	0	0	0	98
.	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	131
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	105
.	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	97
2	0	0	1	0	1	0	1	.	0	0	.	.	0	0	0	0	105
.	0	0	1	0	0	0	.	.	0	0	.	.	0	0	0	0	128
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	106
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	113
1	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	102
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	91
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	116
.	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	97
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	90
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	82
.	0	0	1	0	0	0	.	.	0	0	.	.	0	0	0	0	99
2	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	101
1	0	0	1	0	1	1	2	1	1	1	3	1	0	1	0	0	83
1	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	109
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	116
.	0	0	0	0	2	0	.	.	0	0	.	.	0	0	0	0	82
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	107
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	106
1	0	0	0	0	1	0	1	.	0	0	.	.	0	0	0	0	102
.	0	0	1	0	2	2	.	.	0	0	.	.	0	0	0	0	114
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	74
2	0	0	0	0	1	0	1	.	0	0	.	.	0	0	0	0	99
.	0	0	0	0	2	2	.	.	0	0	.	.	0	0	0	0	78
1	0	0	0	0	0	0	.	.	0	0	0	.	0	0	0	0	104
2	0	0	0	0	0	0	.	.	0	0	.	.	0	0	0	0	94

m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2
100	80	109	93	94	20		17	15	22	16	1	1	0	0	0	0
109	104	104	104	121	35	29	28	32	18	15	1	2	1	0	0	0
118	113	122	118	.	39	41	40	33	36	.	0	.	0	.	0	.
108	85	98	116	145	31	31	30	22	9	17	3	2	1	1	0	1
86	73	85	90	77	24	25	24	26	25	.	0	0	0	0	0	0
115	98	99	127	144	30	21	35	18	23	10	1	2	1	0	0	0
102	98	110	112	123	18	17	13	13	9	10	0	1	0	0	0	0
119	94	105	111	.	21	24	12	13	17	.	0	.	0	.	0	.
106	101	120	164	150	32	21	30	25	13	10	1	2	0	0	0	0
92	98	109	97	91	39	30	30	29	21	7	0	1	0	0	0	0
132	84	97	115	152	32	32	27	12	20	5	2	2	1	0	0	0
92	101	106	116	135	25	33	26	27	8	13	2	3	0	0	0	0
117	130	.	147	157	28	15	17	.	7	5	3	3	1	1	0	1
112	107	106	104	136	36	17	32	22	13	7	1	1	0	0	0	0
126	98	114	94	152	37	30	35	31	15	13	2	2	1	1	0	1
103	73	72	112	132	30	24	37	24	13	10	2	0	1	0	0	0
140	124	140	138	160	17	35	13	32	11	7	2	2	1	0	0	0
112	82	109	119	125	30	28	24	26	10	13	3	2	0	0	0	0
101	84	97	101	122	32	27	31	31	10	12	2	2	0	0	0	0
115	90	104	100	114	36	27	35	25	25	13	2	2	1	1	0	0
102	87	95	106	125	33	35	39	37	21	24	2	1	0	0	0	0
115	103	103	112	142	28	27	33	33	18	12	2	2	0	0	0	0
99	76	81	105	108	38	35	37	35	27	16	2	1	1	0	0	0
100	81	96	102	126	33	26	33	26	11	10	2	2	0	0	0	0
114	68	90	86	116	27	19	25	18	10	25	0	0	0	0	0	0
86	86	85	110	144	32	29	30	26	24	22	1	1	0	0	0	0
114	93	102	103	125	17	15	23	20	10	7	3	2	0	0	0	0
90	90	75	131	144	26	25	21	23	12	12	3	2	2	1	0	0
108	75	82	116	148	27	14	23	12	13	8	3	2	1	0	0	0
112	91	86	109	.	43	28	42	24	42	.	0	.	0	0	0	0
88	78	77	105	.	30	24	32	29	15	.	0	1	0	0	0	.
110	95	92	133	115	28	18	28	12	20	28	1	0	0	0	0	0
101	93	90	108	118	29	23	24	23	15	16	1	1	0	0	0	0
107	85	99	128	136	23	14	23	17	9	10	1	2	1	0	0	0
108	108	92	121	125	39	38	36	29	36	31	0	.	0	0	0	0
76	56	63	75	102	27	20	27	22	19	9	0	0	0	0	0	0
103	106	93	113	.	27	14	21	17	18	.	1	1	0	0	0	0
77	78	67	97	.	27	25	23	26	22	.	0	1	0	.	0	.
108	101	94	112	146	27	19	23	17	17	13	3	2	1	0	0	0
90	90	94	96	100	26	22	14	15	12	14	2	2	1	1	0	0

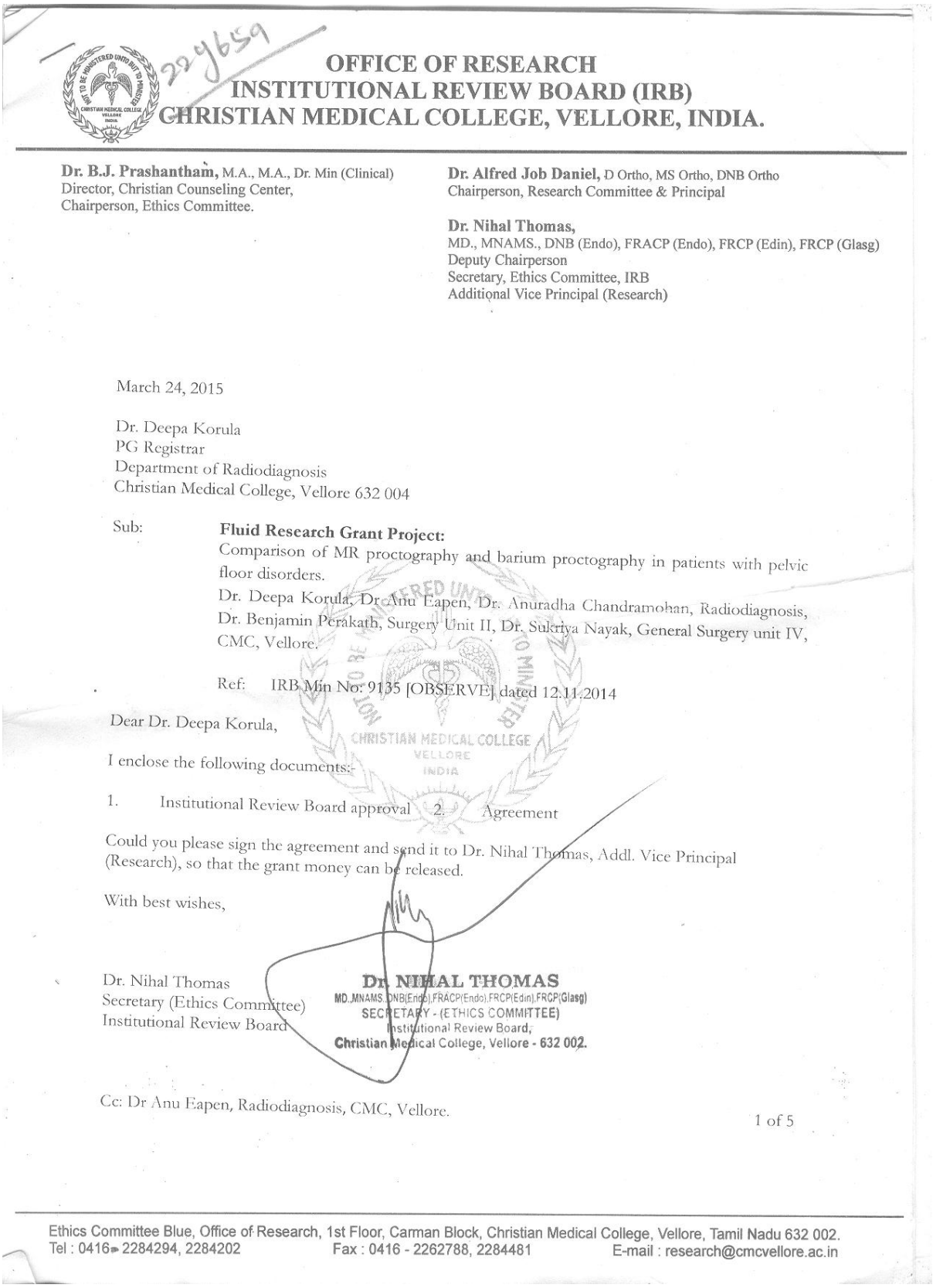
m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2	m_obs1	m_obs2_otherpath
.	.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	NIL	Nil
.	.	0	0	1	0	0	0	0	0	0	0	0	0	0	0	nil	Nil
.	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	nil	Patient was unable to defecate on table hence could not
.	0	0	0	1	0	0	0	0	0	0	0	1	0	0	NIL	nil	
.	.	0	0	0	0	0	0	0	0	0	0	1	0	0	NIL	Had difficulty defecating, canal length not assessed	
.	.	0	0	0	0	0	0	0	0	0	0	0	0	0	nil	Nil	
.	.	0	0	0	0	0	0	0	0	0	0	0	0	0	NIL	Nil	
.	.	0	.	0	.	0	.	0	.	0	.	0	.	NIL	Could not defecate		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	0	NIL	Post hysterectomy status	
.	.	0	0	0	0	0	0	0	0	0	0	0	0	0	NIL	Nil	
.	.	0	0	1	0	0	0	0	0	0	0	0	1	NIL	Mild thinning of the right external sphincter		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	Nil		
.	1	0	0	1	0	0	0	0	0	0	1	0	0	NIL	Squeezing phase was suboptimal		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	nil	Nil		
.	0	0	0	1	0	0	0	0	0	0	0	0	0	NIL	Nil		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	NIL	NIL		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	Nil		
.	.	0	0	1	1	0	0	0	0	0	0	0	0	NIL	Nil		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	nil	Nil		
0	.	0	0	1	0	0	0	0	0	0	0	0	0	NIL	nIL		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	nIL		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	NIL		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	NIL		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	NIL	NIL		
.	.	0	0	0	1	0	0	0	0	0	0	0	0	NIL	nil		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	nil		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	nil	nil		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	nil	nil		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	NIL	nil		
.	.	0	0	0	0	0	0	0	0	0	.	0	0	NIL	not able to defecate so may be innacurate values		
.	.	0	.	0	.	0	.	0	.	0	.	0	0	nil	unable to defecate so innacurate evaluation		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	nil	nil		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	nil		
.	.	0	0	1	0	0	0	0	0	0	0	0	0	NIL	nil		
.	.	0	0	0	0	0	0	0	0	0	0	0	0	NIL	did not defecate well so values unreliable		
.	.	0	0	0	0	0	0	0	0	0	0	0	0		nil		
.	.	0	0	1	.	0	.	0	.	0	.	0	.		patient was unable to defecate hence values not assesse		
.	.	0	.	0	.	0	.	0	.	0	.	0	0		unable to defecate hence all values not assessed		
.	.	0	0	0	0	0	0	0	0	0	0	0	0				
.	0	0	0	0	0	0	0	0	0	0	0	0	0				

age	gender	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_	b_obs2_	b_obs1_
29	1	0	0	5.4	3.6	.	.	0	0	110	112	132	108	104	121	1	2	0
53	0	1	0	6.7	5.8	1	.	0	0	119	100	132	87	119	158	2	2	1
35	1	1	0	7	5.8	1	.	0	1	100	110	112	106	103	123	0	2	0
35	0	0	0	5.6	5.5	.	.	0	0	120	109	116	102	134	180	3	2	1
34	1	0	0	4.4	3.5	.	.	0	0	96	133	94	137	96	180	1	2	0
40	0	0	0	5.5	3.7	.	.	0	0	106	101	100	99	142	150	2	0	0
28	1	0	0	4.6	4.7	.	.	0	0	99	104	116	102	123	155	1	0	0
54	1	0	1	5.4	6.2	.	1	1	0	125	107	91	94	126	120	1	2	0
44	0	1	0	7.8	5.4	1	.	0	0	146	114	148	102	142	150	1	0	0
27	1	0	0	5.6	3.6	.	.	0	0	98	113	100	110	121	123	1	1	0
23	0	1	0	6.4	5.3	1	.	0	0	102	101	116	97	133	128	2	2	1
56	0	1	1	9.4	9.8	2	2	1	2	128	95	101	112	135	175	2	1	0
31	0	1	0	6	5	1	.	1	0	130	120	123	102	156	180	1	2	0
23	1	1	0	6.2	2.9	1	.	0	0	95	107	99	103	118	131	1	0	0
64	0	1	1	7.4	7.5	1	1	2	1	135	140	135	102	114	144	2	3	1
47	0	1	0	6.2	3	1	.	0	0	85	99	95	93	135	143	3	2	0
44	0	1	1	7.3	7.5	1	1	1	1	126	114	112	94	125	143	2	3	0
62	1	0	0	5	4.3	.	.	0	0	103	101	103	95	128	141	1	1	0
30	1	0	0	5.7	4.5	.	.	0	0	87	99	116	93	107	126	2	2	0
45	0	0	1	5.9	6.1	.	1	0	1	119	103	121	.	123	124	2	2	1
49	1	0	0	5	3.6	.	.	0	0	94	100	76	82	85	123	0	0	0
41	1	0	0	4.3	4.6	.	.	0	0	125	125	118	107	120	133	2	2	0
42	0	1	0	6.8	5.8	1	.	1	1	105	139	120	128	123	142	2	2	0
29	1	1	0	6.7	3	1	.	1	0	107	107	110	96	121	141	2	2	0
29	1	0	0	4.8	3.6	.	.	1	0	110	104	105	96	115	139	2	2	0
61	0	1	1	6.7	6.2	1	1	0	0	131	109	124	101	138	153	3	3	1
50	0	1	1	8	7	2	1	0	0	117	110	131	90	147	166	3	3	1
57	0	1	0	6.6	5.5	1	.	1	1	122	137	124	101	135	139	2	1	0
32	0	1	0	6.8	4.8	1	.	0	0	107	90	89	84	125	173	1	2	0
56	1	1	1	7.3	6.5	1	1	0	0	110	105	94	91	127	125	1	1	0
69	1	1	0	7.5	5.9	1	.	1	1	129	121	103	118	120	157	1	1	0
34	1	0	0	5.3	3.4	.	.	0	0	136	100	116	97	139	.	0	1	0
38	1	1	0	8.3	5	2	.	0	0	114	105	132	90	124	135	2	2	0
38	0	0	0	4.7	4.3	.	.	0	0	89	90	89	87	136	141	2	2	1
75	1	1	0	7.3	4.7	1	.	1	1	112	129	110	110	145	170	2	1	0
21	1	0	0	4	5.8	.	.	0	0	98	92	116	85	120	123	1	0	0
40	0	1	1	6.5	6.8	1	1	1	1	121	119	97	100	142	140	3	3	1
41	1	1	0	7	5.2	1	.	0	0	96	101	104	93	123	160	3	3	0
60	0	1	1	9.5	6.8	2	1	2	2	103	119	110	89	124	169	3	3	1
41	0	0	0	4.2	3	.	.	0	0	103	139	100	134	143	160	1	1	0

b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2	b_obs1	b_obs2
0	0	0	0	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
1	0	0	0	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	0	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
1	0	1	.	0	0	0	1	1	0	0	0	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	0	1	0	0	0	0	0	0	.	0	nil	nil
1	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	NIL	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	NIL	nil
1	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
1	0	0	.	.	0	0	1	1	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
1	0	1	.	0	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	1	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	0	.	0	NIL	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	1	.	0	nil	NIL
0	0	0	.	.	0	0	0	0	0	0	0	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	1	1	0	0	0	0	0	0	.	0	NIL	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
0	0	0	.	.	0	0	1	0	1	0	1	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	1	.	0	NIL	nil
0	0	0	.	.	0	0	1	0	1	0	1	1	0	1	.	0	nil	nil
0	0	0	0	.	0	0	1	0	0	0	0	0	0	0	.	0	nil	nil
1	0	0	.	.	0	0	0	0	0	0	0	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	0	1	0	0	0	0	0	1	.	0	nil	nil
0	0	0	.	.	0	0	0	0	0	0	0	0	0	1	.	0		nil
1	0	0	.	.	0	0	1	1	1	0	0	0	0	0	0	0		
0	0	0	.	.	0	0	0	0	0	0	0	0	0	0	0	0		
2	1	0	0	.	0	0	1	0	0	0	0	0	0	0	0	0		
0	0	0	.	.	0	0	1	b	0	0	0	0	0	0	0	0		

Appendix 6:

IRB APPROVAL:



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Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

March 24, 2015

Dr. Deepa Korula
PG Registrar
Department of Radiodiagnosis
Christian Medical College, Vellore 632 004

Sub: **Fluid Research Grant Project:**
Comparison of MR proctography and barium proctography in patients with pelvic floor disorders.
Dr. Deepa Korula, Dr. Anu Eapen, Dr. Anuradha Chandramohan, Radiodiagnosis, Dr. Benjamin Perakath, Surgery Unit II, Dr. Sukriya Nayak, General Surgery unit IV, CMC, Vellore.

Ref: IRB Min No: 9135 [OBSERVE] dated 12.11.2014

Dear Dr. Deepa Korula,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr Anu Eapen, Radiodiagnosis, CMC, Vellore.

1 of 5

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

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Ref: IRB Min No: 9135 [OBSERVE] dated 12.11.2014

Dear Dr. Deepa Korula,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Comparison of MR proctography and barium proctography in patients with pelvic floor disorders. " on November 12th 2014.

The Committees reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. Deepa Korula, Anuradha Chandramohan, Benjamin Perakath, Sukriya Nayak.
3. Informed Consent form (English, Tamil, Hindi & Bengali)
4. Information Sheet(English, Tamil, Hindi & Bengali)
5. Proforma
6. No of documents 1-5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on November 12th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events,** occurring in the course of the project, **annual report,** any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Fluid Grant Allocation:

A sum of 1, 00,000/- INR (Rupees One Lakh Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an 1st installment. The rest of the 50,000/- INR (Rupees Fifty Thousand only) each will be released at the end of the first year as 2nd installment following the receipt of the Interim progress/ Annual report and subsequent submission of it to the IRB.

Yours sincerely

CHRISTIAN MEDICAL COLLEGE VELLORE INDIA

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
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Cc: Dr Anu Eapen, Radiodiagnosis, CMC, Vellore.

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